## Cochise Regional Hospital

### LABORATORY POLICIES AND PROCEDURES

#### TABLE OF CONTENTS

**GENERAL POLICIES**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope of Services</td>
<td>4</td>
</tr>
<tr>
<td>Staffing Plan</td>
<td>8</td>
</tr>
<tr>
<td>Delegation of Duties</td>
<td>11</td>
</tr>
<tr>
<td>Handling of Proficiency Testing Materials</td>
<td>13</td>
</tr>
<tr>
<td>Proficiency Testing Follow-Up</td>
<td>14</td>
</tr>
<tr>
<td>Directorship for Laboratory Services</td>
<td>18</td>
</tr>
<tr>
<td>Authorization to Sign Log Sheets, Quality Control and</td>
<td>19</td>
</tr>
<tr>
<td>Proficiency Testing Attestation Statement</td>
<td></td>
</tr>
<tr>
<td>Request for Laboratory Services</td>
<td>21</td>
</tr>
<tr>
<td>Minimum Requirements for a Laboratory Order</td>
<td>22</td>
</tr>
<tr>
<td>Laboratory Result Reports</td>
<td>24</td>
</tr>
<tr>
<td>STAT Policy</td>
<td>25</td>
</tr>
<tr>
<td>Critical/ Panic Values</td>
<td>28</td>
</tr>
<tr>
<td>Protocol for Contacting Lab Personnel after Normal Hours of</td>
<td>32</td>
</tr>
<tr>
<td>Operation</td>
<td></td>
</tr>
<tr>
<td>Utilization of Reference Laboratories</td>
<td>33</td>
</tr>
<tr>
<td>HIV, HCV and CHAGAS Lookback Procedure</td>
<td>34</td>
</tr>
<tr>
<td>Microbiology Specimens</td>
<td>37</td>
</tr>
<tr>
<td>Unable to Perform In-House</td>
<td>38</td>
</tr>
<tr>
<td>Instrument Preventative Maintenance</td>
<td>40</td>
</tr>
</tbody>
</table>
Cochise Regional Hospital

Laboratory Policies

Scope of Services

POLICY

The clinical laboratory provides 24 hour a day, 7 day a week services to inpatients. Outpatient service is from 06:00 to 21:00. A pathologist is available on call for clinical and/or anatomic pathology services.

TYPES OF CUSTOMERS

Patients served include neonatal, pediatric, adolescent, adult and geriatric. The Laboratory evaluates test results for appropriateness based on diagnosis, condition, age, gender, and previous test results. The Laboratory assures accuracy by daily quality control on analytical runs and external proficiency testing to correlate values with national standards.

PROCEDURES/SERVICES

Laboratory services include:

- Collecting blood specimens
- Analyzing blood and body fluids in the areas of routine chemistry, hematology, blood gas analysis and urinalysis
- Preparing blood and blood products for transfusion
- Collecting urine drug screens for outside businesses and agencies

Services that are referred to outside accredited agencies include:

- All anatomic pathology services including histology and cytology
- Parasitology
- Microbiology (anaerobe, AFB mycology. virology)
- Immunology
- Esoteric testing
# Cochise Regional Hospital

## Laboratory Policies

### TESTS PERFORMED

<table>
<thead>
<tr>
<th>CHEMISTRY</th>
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<tbody>
<tr>
<td>Acetaminophen (Tylenol)</td>
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<tr>
<td>Liver Profile</td>
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<tr>
<td>Acetone</td>
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<tr>
<td>Magnesium</td>
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<tr>
<td>Albumin</td>
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<tr>
<td>Microalbumin</td>
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<tr>
<td>Alkaline Phosphatase</td>
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<tr>
<td>Micro-Total Protein</td>
</tr>
<tr>
<td>ALT (SGOT)</td>
</tr>
<tr>
<td>Phosphorus (PO4)</td>
</tr>
<tr>
<td>Ammonia</td>
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<tr>
<td>Potassium (K)</td>
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<td>PSA</td>
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<td>AST (SGOT)</td>
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<tr>
<td>RA Factor</td>
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<tr>
<td>Basic Metabolic Profile</td>
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<tr>
<td>Rubella IgG</td>
</tr>
<tr>
<td>Beta HCG, quantitative</td>
</tr>
<tr>
<td>Salicylate (Aspirin)</td>
</tr>
<tr>
<td>Bilirubin, Total, Direct, Neonatal has Neonatal</td>
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<tr>
<td>Serum Pregnancy (qualitative)</td>
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<tr>
<td>BNP</td>
</tr>
<tr>
<td>Sodium (NA)</td>
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<tr>
<td>BUN</td>
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<tr>
<td>Troponin</td>
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<tr>
<td>Calcium</td>
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<tr>
<td>Theophylline</td>
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<tr>
<td>Carbamezapine (Tegretol)</td>
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<tr>
<td>Triglycerides</td>
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<tr>
<td>Carbon Dioxide (CO2)</td>
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<tr>
<td>TIBC</td>
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<tr>
<td>Chloride (Cl)</td>
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<td>Comprehensive Metabolic Profile</td>
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<td>CPK</td>
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<td>Creatine</td>
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<td>Creatine Clearance</td>
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<td>CSF Glucose</td>
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<td>Dilantin (Phenytoin)</td>
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<td>Drug of Abuse (DOA)</td>
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<td>FT4</td>
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<td>Gentamicin</td>
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<td>Lipase</td>
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<tr>
<td>Crossmatch</td>
<td>Direct Coombs (DAT)</td>
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<tr>
<td>Fresh Frozen Plasma</td>
<td>Type and Screen</td>
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<tr>
<td>Platelet Pheresis</td>
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</tr>
</tbody>
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<table>
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<td>C. Difficile Toxin A</td>
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<td>Fecal/Gastric Occult Blood</td>
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<td>Hemoglobin</td>
<td>Gram Stain</td>
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<tr>
<td>Hematocrit</td>
<td>H. pylori</td>
</tr>
<tr>
<td>Manual Differential</td>
<td>Influenza A and B</td>
</tr>
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<td>-----------------------------</td>
<td>-------------------</td>
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<tr>
<td>Platelet Count</td>
<td>KOH prep</td>
</tr>
<tr>
<td>Sed Rate (ESR)</td>
<td>Rapid Strep Screen</td>
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<tr>
<td>RSV antibody</td>
<td>Fecal Lactoferrin</td>
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<th>URINALYSIS</th>
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<td>D.Dimer</td>
<td>Urine Dip Stick</td>
</tr>
<tr>
<td>Protime (PT)</td>
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<td>Partial Thromboplastin (PTT)</td>
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Revised: 5/09, 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Staffing Plan

POLICY

It is the policy of Cochise Regional Hospital to provide adequate staffing to provide quality laboratory services.

SKILL LEVELS

The Medical Director (Pathologist) is available by phone at all times and can be reached at 432-1984. The Medical Director directs the Blood Bank and assists the Head of Laboratory Services (Laboratory Manager) in directing the Clinical Laboratory.

The Head of Laboratory Services (Laboratory Manager) manages the Clinical Laboratory and Blood Bank and technically directs the Laboratory with assistance from the Medical Director.

Laboratory staffing includes medical laboratory technicians/technologists, phlebotomists, and laboratory assistants. The complexity of each task determines the skill level to perform it.

STAFFING PLAN

The laboratory is staffed by personnel that have been trained and oriented to the department and includes supervisory personnel, staff technologist, laboratory assistants and phlebotomists. Full and part time personnel are utilized to provide adequate coverage for the average workload. Staffing levels are based on the volume and complexity of the laboratory services.

MINIMAL TRAINING REQUIREMENTS

Medical Technologist: Bachelors Degree in any area of the following life sciences:

a) Physics

b) Biology

c) Chemistry

Medical Laboratory Technician: Associates Degree in Medical Laboratory Technology
Lab Assistant: High School Diploma and/or certificate in Medical Assisting/Patient Care Technician

Phlebotomist: High School Diploma and/or certificate accredited phlebotomy program.

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Revised: 5/09, 12/13, 06/14
# SKILL MIX PLAN

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<th>Title</th>
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<th>Tue</th>
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<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
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<tr>
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<tr>
<td>PRN Phlebotomist (Weekend days)</td>
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Revised: 5/09, 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Delegation of Duties

POLICY

The Laboratory at Cochise Regional Hospital utilizes professional job tiers to define appropriate job duties and chain of command within the department.

The Laboratory Manager has established a list of responsibilities as follows:

LABORATORY MEDICAL TECHNOLOGIST

- The qualified technologist is delegated to be responsible for those duties assigned in this individual's job description.

- Supervision of this individual, when necessary, during any phase of specimen processing, test performance or reporting of patient test results, will be the responsibility of the Medical Technologist Team Leader, and/or Laboratory Manager.

LABORATORY ASSISTANT

- The qualified laboratory assistant is delegated to be responsible for those duties assigned in this individual's job description.

- Supervision of this individual, when necessary, during any phase of specimen processing, or reporting of patient test results, will be the responsibility of the technologist on duty, the Medical Technologist Team Leader, and/or Laboratory Manager.

PHLEBOTOMIST

- The qualified phlebotomist is delegated to be responsible for those duties assigned in this individual's job description.

- Supervision of this individual, when necessary, during any phase of specimen processing or reporting of patient test results, will be the responsibility of the technologist on duty, the Medical Technologist Team Leader, and/or Laboratory Manager.
Cochise Regional Hospital

Laboratory Policies

Handling of Proficiency Testing Materials

POLICY

It is the policy of Cochise Regional Hospital lab to perform proficiency testing on all analytes done in house.

PRINCIPLE

Proficiency testing is performed to determine how our laboratory results compare with other laboratories that use the same methodologies. This helps the Laboratory Manager identify performance problems not recognized by internal mechanism.

PROCEDURE

Cochise Regional Hospital contracts with American Proficiency Institute to provide a HCFA accredited and approved proficiency program. All analytes performed as CRH will be enrolled in the proficiency testing program.

All proficiency materials will be analyzed and treated using the same methods and procedures as the patient samples performed at CRH. Proficiency samples are introduced into the flow of the laboratory and treated as patient samples. Proficiency samples are never sent to another laboratory for repeat testing or verification of results. (Even if our policy would require us to do so). Proficiency testing materials should be frozen and stored until the results of the survey return from American Proficiency Institute (for troubleshooting purposes).

Results on the completed survey will be given to the Laboratory Manager for final interpretation. The proper documentation of results will be filled out and verified by another technologist to assure no clerical errors were made. Returned survey results will be reported at departmental meetings. Erroneous results are checked for clerical errors, rerun as appropriate, slides reviewed with staff and the pathologist, and corrective action will be taken. Corrective actions will be reviewed at departmental meetings for educational purposes. All proficiency results will be reviewed and signed by the Medical Laboratory Director.

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Cochise Regional Hospital
Laboratory Policies

Proficiency Testing Follow-Up

POLICY

It is the policy of the Laboratory at Cochise Regional Hospital to conduct investigations of all proficiency testing that is unacceptable (80% and below for all analytes and below 100% for Blood Banking).

PRINCIPLE

Proficiency testing occurs in the Laboratory in order to maintain accurate and precise performance of all tests. This process helps to maintain a level of performance for instrumentation as well as for those performing those tests by utilizing unacceptable proficiency testing as a market for weak areas of performance.

SUMMARY

Should any proficiency testing come back unacceptable. A review or investigation must be conducted by the Laboratory Manager. The proficiency Testing Corrective Action Form and Checklist must be filled out with information pertaining to the particular testing which was unacceptable. All findings are to be recorded by the Laboratory Manager and reviewed with the Laboratory Director. Documentation will be kept with the quarterly proficiency testing results as well as copy to the Quality/Risk Committee and Quality Council.

The following parameters are reviewed in the event that a proficiency test is unacceptable:

1. Quality control
2. Calibrations
3. Tech performance and competency

If a technologist was in error during performance of proficiency testing, retraining is the appropriate form of action, If it is determined that quality control and/or calibrations factored into this problem, a review of all quality control/calibrations for that clay would be appropriate. If it is determined that an undetectable problem with instrumentation was the cause, the instrument manufacturer must be contacted for any service related
issues. Repeat testing of any analyte that was unacceptable during proficiency testing must also take place in order to determine if clerical, technical, or instrumentation failure occurred. Should it be determined that the proficiency testing material was contaminated or quantity not sufficient, the American Proficiency Institute should be contacted to request a new sample or to report the problem. Graded proficiency testing is sent to the Laboratory Director for review as well as to the CEO,
Checklist for Corrective Action

Year/Testing Event  Analyte  Sample number
Date Sample Tested  Person Performing Test

Specimen Handling
Were specimens received in an acceptable condition? Yes O No O
Were specimens stored according to the instructions on the result forms? Yes O No O
Were the samples hemolyzed? Yes O No O
Were samples tested within the time allowed for sample stability? Yes O No O
If applicable, were the samples reconstituted correctly? Yes O No O

Notes:

Clerical Errors
Were the results transcribed onto the forms correctly? Yes O No O
Were the results recorded on the correct result form? Yes O No O
Was the correct instrument/reagent/kit selected? Yes O No O
Were the results recorded in the correct units? Yes O No O
Were the results on your evaluation the same as the results you reported? Yes O No O

Notes:

Quality Control
Were controls in range on the date the proficiency samples were tested? Yes O No O
Is there any indication of trending or shifting of the control results? Yes O No O

Notes:

Calibration
Were there any problems with the most recent calibration? Yes O No O
When was the last calibration performed?
How often is a calibration performed?
When was the last calibration verification performed?

Notes:

Instrument

Were instrument problems noted the day the samples were tested?  Yes O No O

Has there been any recent maintenance on the analyzer?  Yes O No O

Have you contacted your analyzer manufacturer for assistance?  Yes O No O

Notes:

Reagents

Were the reagents stored properly?  Yes O No O

Were the reagents expired or was the open vial stability exceeded?  Yes O No O

Have there been any changes in reagent manufacturer or formulation? Yes O No O

Notes:

Culture

Was the media stored according to manufacturer’s instructions?  Yes O No O

Was the media expired?  Yes O No O

Was the appropriate QC performed on the media? Yes O No O

Was the incubator temperature/gas/humidity within acceptable limits?  Yes O No O

If applicable, have you contacted your kit manufacturer for assistance? Yes O No O

Notes:

Findings:

Could patient results have been affected? If so, explain course of action:

Corrective Action:

Person Performing Investigation  Date

Lab Director  Date

Completed correction action forms do not need to be sent to American Proficiency Institute. Keep all documentation with your records. You will be required to show them to your inspector at your next onsite inspection. You may also need to send a copy to your state or accrediting agency. This form is designed to offer assistance to the laboratory in investigation and troubleshooting proficiency testing failures. It is the laboratory’s responsibility to effectively troubleshoot and resolve all proficiency testing failures. Completion of this form does not guarantee future successful performances with proficiency testing. Call 800-333-0958 for assistance.
Cochise Regional Hospital

Laboratory Policies

Directorship for Laboratory Services

POLICY

It is the policy of Cochise Regional Hospital to contract with Sierra Vista Pathology for pathology services.

PROCEDURE

The Laboratory is directed by a Pathologist, Dr. Max Mirot, who is certified by the American Board of Pathology and is a Pathologist with Sierra Vista Pathology. Dr. Mirot is contracted for monthly On-site visits and is readily available by phone for consultation. In his absence, the Laboratory will contact the Pathologist “on call” for Sierra Vista Pathology.

Dr. Mirot is a member of the Medical Staff and attends their meetings regularly. He reviews quality control, charts for utilization review, and facilitates in-services for all Laboratory personnel.

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Reviewed: 11/08, 5/09, 12/13

Revised: 5/09, 12/13, 06/14
Authorization to Sign Log Sheets

Quality Control & Proficiency Testing

Attestation Statement

POLICY

Since a pathologist does not visit CRH laboratory daily or weekly, there may be times when it would be impossible for the Pathologist to sign the Attestation Statement in time for meeting the rigid deadline for submitting proficiency test results. Rather than risk having results submitted voided because of late submission, the Laboratory Manager has the Pathologist’s authorization to sign this statement, with the understanding that it will have entirely the same good faith connotation that the Pathologist’s signature would imply. Furthermore, the Laboratory Manager is authorized to review all laboratory worksheets, logbooks and quality control. It is expected that the Technical Consultant or Technical Supervisor would bring to the Pathologist’s attention any problems that need to be reviewed.

_________________________________
Max Mirot, M.D. (Pathologist Signature)

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Cochise Regional Hospital

Laboratory Policies

Directorship for Laboratory Services

POLICY

It is the policy of Cochise Regional Hospital to contract with United Pathology, Ltd. for pathology services.

PROCEDURE

The Laboratory is directed by a Pathologist, Dr. Max Mirot, who is certified by the American Board of Pathology and is an Associate Pathologist with United Pathology. Dr. Mirot is contracted for monthly on-site visits and is readily available by phone for consultation. In his absence, the Laboratory will contact the Pathologist “on call” for United Pathology at 459-1984.

Dr. Mirot is a member of the Medical Staff and attends their meetings regularly. He reviews quality control, charts for utilization review, and facilitates in-services for all Laboratory personnel.

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Cochise Regional Hospital

Laboratory Policies

Request for Laboratory Services

POLICY

Requests for laboratory services are to be sent to the laboratory, through the order entry system, as soon as possible after patient admission. The laboratory is staffed to provide 24 hour service. If the computer system is not functioning, go to the backup system using paper laboratory requisitions. (See policy for downtime procedure).

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Cochise Regional Hospital

Laboratory Policies

Minimum Requirements for a Laboratory Order

POLICY

Orders for laboratory testing will meet the minimum requirements before testing is performed. This may be accomplished by completing a CRH lab requisition form.

PURPOSE

To ensure appropriate testing is performed and that the correct diagnosis is available for appropriate billing.

PROCEDURE

All laboratory orders will be on a completed CRH laboratory requisition form, or will contain the following information at a minimum:

• Patient name
• Date order was written
• Test(s) to be done
• ICD-9(s) or written diagnosis (reason testing is being done) for each test ordered
• Physician signature (or other individual authorized by law to order tests)

No testing will be performed without complete information.

If a patient comes to CRH for laboratory testing without complete information on the order, every effort will be made to obtain the missing information so the testing process may then continue. The ordering physician or their staff will be contacted to supply the missing information in writing (by fax or mail). Should the physician not be available to provide the information, the patient will then be requested to obtain the written information from their physician before proceeding.

Any test order which is ambiguous, subject to multiple interpretations, or requests a panel(s) which is not currently defined by CPT codes will be clarified with the physician in writing (by fax or mail) to determine exactly what tests are to be performed before
proceeding. All test orders are entered into computer system through order entry under each patient registration or industrial accounts.
Cochise Regional Hospital

Laboratory Policies

Laboratory Result Reports

POLICY

Most reports are available through the hospital computer system at the nursing stations. Manual reports, such as microbiology and reference laboratory reports are scanned into patient charts by laboratory personnel upon completion of the work.

PROCEDURE

Back-up procedure when computer is down:

• Hand written results on paper requisition will be delivered to nursing station by laboratory personnel.

• All results will be put into computer system when it is back on-line and the report will be ready to review through the hospital system.

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Cochise Regional Hospital

Laboratory Policies

STAT Policy

POLICY

All work in the Laboratory is performed either STAT or ROUTINE. All work ordered from the Emergency Room is considered STAT unless indicated otherwise by the patient’s physician.

In the interest of efficient utilization of laboratory personnel and equipment, all profile orders are routinely batched in the laboratory. Any test may be drawn STAT. Only tests on the STAT list will be performed STAT, (see page 2 for STAT list), with the exception of Gram Stains. Spinal Fluid Gram stains will be considered STAT regardless of order. All other gram stains must be ordered STAT.

All STAT tests will be processed and reported out no longer than one (1) hour from receipt of specimen. STAT tests from the Draw Station will be processed within two (2) hours of receipt at the Main Laboratory.

Test marked as ASAP will be processed within two (2) hours from receipt of specimen.

Routine tests will have a turnaround time of one (1) working day, with the exception of those tests not performed in-house and sent to a reference lab.

The Laboratory is to be notified by nursing personnel of all STAT orders.

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## LABORATORY STAT LIST

<table>
<thead>
<tr>
<th>BLOOD BANK</th>
<th>COAGULATION</th>
</tr>
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<tbody>
<tr>
<td>Direct Coombs (DAT)</td>
<td>Partial Thromboplatin (PTT)</td>
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<td>Prothrombin Time (PT)</td>
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<td>CKMB (mass)</td>
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<tr>
<td>CPK</td>
<td>Complete Urinalysis with Reflex micro</td>
</tr>
<tr>
<td>Creatinine</td>
<td></td>
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<tr>
<td>CSF Protein</td>
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</tr>
<tr>
<td>Electrolytes</td>
<td>C. Difficile</td>
</tr>
<tr>
<td>Glucose</td>
<td>Drawing of Blood Cultures</td>
</tr>
<tr>
<td>Lipase</td>
<td>Fecal Occult Blood</td>
</tr>
<tr>
<td>Magnesium</td>
<td>H.pylori</td>
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<tr>
<td>Pregnancy Test</td>
<td>Influenza A and B</td>
</tr>
<tr>
<td>Basic Metabolic Profile</td>
<td>Monotest</td>
</tr>
<tr>
<td>Salicylates</td>
<td>RSV</td>
</tr>
<tr>
<td>Test</td>
<td>Method</td>
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<td>-------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>SGOT</td>
<td>Gram Stains</td>
</tr>
<tr>
<td>SGPT</td>
<td>Strep Screen</td>
</tr>
<tr>
<td>Therapeutic Drug Levels</td>
<td>Wet Prep/KOH</td>
</tr>
<tr>
<td>Tronponin</td>
<td></td>
</tr>
<tr>
<td>Uric Acid</td>
<td></td>
</tr>
<tr>
<td>Urine Drug Screen (Qualitative)</td>
<td></td>
</tr>
<tr>
<td>Amphetamine/Methamphetamine; Barbituates; Benzodiazepine; Cocaine; Cannabinoids; Opiates; Phencyclidine</td>
<td></td>
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</tbody>
</table>
Cochise Regional Hospital

Laboratory Policies

Critical/Panic Values

POLICY

The following specifies laboratory results which are to be called to the attention of the nurse of physician in charge of the patient under study. Nursing units will then notify the patient’s physician.

For all outpatients, it is the responsibility of the medical technologist/technician running the test to repeat any critical value and upon confirmation to immediately call the physician or the physician’s office with the result(s). It is also the responsibility of the medical technologist/technician to call any critical results upon verification to any physician after hours. Physician numbers and on call doctors can be found on the call sheet.

Hematocrit: less than 20%
Hemoglobin: less than 7.0g/dl
Platelets: less than 40.0 x 10^3/ml; greater than 999.0 x 10^3/ml
WBC: less than 1,000; greater than 30,000
Protime: non-therapeutic: greater than 18 seconds
          therapeutic: greater than 30 seconds
PTT: greater than 45 seconds
BUN: greater than 100 mg/dl
Calcium: less than 7.0 mg/dl; greater than 12.0 mg/dl
Creatinine: greater than 5.0 mg/dl
Glucose: less than 40 mg/dl; greater than 400 mg/dl
Magnesium: less than 1.0 mg/dl; greater than 5.0 mg/dl
          Phosphorus: less than 1.0 mg/dl; greater than 9.0 mg/dl
Potassium: less than 2.0 mmol/L; greater than 6.0 mmol/L,
Sodium: less than 120 mmol/L; greater than 160 mmol/L

Therapeutic Drug Levels: greater than the therapeutic range

Blood Bank: inability to find compatible blood for crossmatch (to include positive antibody screens)

Gram Stain: positive for blood cultures and CSF cultures

When calling any critical result, the results must be read back in order to determine that the receiver has understood what was given. Documentation into the computer system must occur after the results have been called and must include the full name and position of the person receiving information including read back, date/time called and location. In addition, any other action taken by a tech must also be documented into the computer system. Critical values will be monitored daily by the Laboratory Manager or designee.

Blood Bank:

Positive Antibody Screen
Positive Direct Coombs
Confirmed transfusion reactions (bring to immediate attention of pathologist)
Bacterial contaminated blood unit bags (bring to immediate attention of pathologist)

Chemistry:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>less than</th>
<th>greater than</th>
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<tbody>
<tr>
<td>Acetaminophen</td>
<td>N/A</td>
<td>&lt;100 ug/dl</td>
</tr>
<tr>
<td>Acetone</td>
<td>N/A</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Ammonia</td>
<td>N/A</td>
<td>100 mg/dl</td>
</tr>
<tr>
<td>Bilirubin, neonatal</td>
<td>N/A</td>
<td>12 mg/dl</td>
</tr>
<tr>
<td>BUN</td>
<td>N/A</td>
<td>100 mg/dl</td>
</tr>
<tr>
<td>Calcium</td>
<td>6.0 mg/dl</td>
<td>13.0 mg/dl</td>
</tr>
<tr>
<td>CO2</td>
<td>N/A</td>
<td>40M mmol/L</td>
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<tr>
<td>Substance</td>
<td>Value</td>
<td>Reference Value</td>
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</tr>
<tr>
<td>Creatine</td>
<td>N/A</td>
<td>7.5 ing/dl</td>
</tr>
<tr>
<td>Digoxin</td>
<td>N/A</td>
<td>2.5 ng/dl</td>
</tr>
<tr>
<td>Dilantin/Phenytoin</td>
<td>N/A</td>
<td>21.0 ug/dl</td>
</tr>
<tr>
<td>Ethanol</td>
<td>N/A</td>
<td>400 mg/dl</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>N/A</td>
<td>12.0 mg/dl</td>
</tr>
<tr>
<td>Glucose</td>
<td>40 mg dl</td>
<td>400 mg/dl</td>
</tr>
<tr>
<td>Magnesium</td>
<td>1.0 mg/dl</td>
<td>5.0 mg/dl</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>N/A</td>
<td>50.0 ug/ml</td>
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<tr>
<td>Phosphorus</td>
<td>1.0 mg/dl</td>
<td>9.0 mg/dl</td>
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<tr>
<td>Potassium</td>
<td>2.8 mmol/L</td>
<td>6.2 mmol/L</td>
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<td>Salicylate</td>
<td>N/A</td>
<td>50.0 mg/dl</td>
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<tr>
<td>Sodium</td>
<td>120 mg/dl</td>
<td>160.0 mg/dl</td>
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<tr>
<td>Tegretol/Carbamazapine</td>
<td>N/A</td>
<td>15.0 ug/dl</td>
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<tr>
<td>Theophylline</td>
<td>N/A</td>
<td>21.0 ug/dl</td>
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<tr>
<td>Valproic Acid</td>
<td>N/A</td>
<td>200.0 ug/ml</td>
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<tr>
<td>Troponin</td>
<td>N/A</td>
<td>&gt;0.5 ng/ml</td>
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</table>

**Hematology:**

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<thead>
<tr>
<th>Analyte</th>
<th>less than</th>
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<tbody>
<tr>
<td>Hematocrit</td>
<td>20%</td>
<td>60%</td>
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<tr>
<td>Hemoglobin</td>
<td>7.0 g/dL</td>
<td>20.0 g/dL</td>
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<tr>
<td>Platelets</td>
<td>40.0 x 10^3/ml</td>
<td>999.0 x 10^3/ml</td>
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<tr>
<td>Protime</td>
<td>N/A</td>
<td>60.5 sec</td>
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<tr>
<td>Protime (INR)</td>
<td>N/A</td>
<td>3.5</td>
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<tr>
<td>PTT</td>
<td>N/A</td>
<td>100.0 sec</td>
</tr>
<tr>
<td>WBC</td>
<td>1.0 x 10^3/ml</td>
<td>30.0 x 10^3/ml</td>
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</tbody>
</table>

References:

1. Source: (C 1-): Courtesy of Judy Sikes, PhD, CPHQ, Director of Accreditation/Medical Staff Services, Parkview Medical Center, Pueblo, Colorado.

2. Medical Laboratory Management Forms, Checklists, and Guidelines, Supplement #13, November 2004, pgs: 4:77-4:78


   Jacques Wallace, MD

Effective Date: 3/98

Reviewed: 11/08, 5/09, 12/13

Revised: 5/09, 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Protocol for Contacting Lab Personnel After Normal Hours of Operation

POLICY

The laboratory is staffed 24 hours a day seven days a week. In the event it becomes necessary to contact lab personnel after the normal hours of operation of the laboratory, the following protocol is to be followed:

1. Dial the Laboratory Extensions (5736, 5737, 5738, or 5935). The possibility exists that
the tech is in the Laboratory.

2. If, after a reasonable period of time a tech CANNOT be reached by phone, a call to the Laboratory Manager should be made by phone. The Lab Manager’s cell phone number is located on the hospital call list. Check call schedule for home/cell information for Laboratory Manager.

3. If after two unsuccessful tries to reach the Laboratory Manager and allowing a reasonable amount of time for response, dial the home phone number of the Administrator on call.

Calling persons OTHER than those in-house should be done ONLY as a last resort in cases of emergency. Following protocol and using common sense should facilitate contacting Laboratory personnel after normal hours of operation.

Effective Date: 3/98

Reviewed: 11/08, 5/09, 12/13

Revised: 5/09, 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Utilization of Reference Laboratories

POLICY

The Laboratory at Cochise Regional Hospital utilizes the following outside reference laboratories to perform testing that cannot be done in house.

United Pathology  CLIA# 03D0713539
75 Colonia de Salud, Ste. D200
Sierra Vista, AZ 85636

Arizona State Laboratory Services  CLIA# 03D0641866
1520 W. Adams Street
Phoenix, AZ 85007

Sierra Vista Regional Health Center  CLIA# 03D0669190
300 El Camino Real
Sierra Vista, AZ 85635

Copper Queen Hospital  CLIA# 03D05311844
101 Cole Avenue
Bisbee, AZ 85603
Cochise Regional Hospital

Laboratory- Blood Bank Policies and Procedures

Title: HIV, HCV and CHAGAS Lookback Procedure

Policy:

It is the policy of Cochise Regional Hospital to notify any recipient of potentially infectious blood, blood products or tissues of the potential exposure in compliance with all regulatory standards.

Purpose:

All blood, blood products and tissues used for transfusion or infusion at Cochise Regional Hospital (CRH) are derived from donors who, at the time of donation, were tested for the presence of diseases which might be transmitted through their donation. Testing includes Human Immunodeficiency Virus (HIV-the virus responsible for AIDS), Hepatitis C (HCV) and Trypanosoma cruzi (a parasite responsible for the disease Chagas).

Although the tests utilized for HIV and HCV testing are very sensitive it is possible that the donation might have occurred very early in the donor’s disease when these tests are not sensitive enough to detect the presence of an infectious process. With the case of Chagas, the Chagas Prevalence Study protocol for donor testing has been reviewed and approved by the American Red Cross Institutional Review Board. The Board has considered the donor human subject aspects of this study and the FDA’s request to provide identification, notification and testing for recipients of prior components from confirmed positive donors.

The period of time between the initial infection and the development of changes sufficient enough for detection is known as the “window” period. Should an infected donor who made a donation through this window period return for a second donation at a later time, testing would then show positive results and would indicate the possibility that the donor might have been infectious at the previous donation. Should such a situation arise, the donor’s most recent donation would be subjected to an additional “confirmatory” test and if the infection is confirmed, Federal mandates require notification of the recipient of prior donations (donations within the previous 5 years) so that they might be tested for infection and counseled regarding the implications of the exposure, treatments available and ways to limit the spread of the disease to others.
Procedure:

In the event that the CRH Blood Bank is informed by the American Red Cross that potentially infectious products have been provided, Blood Bank personnel will:

1. Immediately advise the Medical Director of the Laboratory and the Laboratory Manager.

2. Immediately search through the Blood Bank stock to find any implicated unit(s).

3. If found quarantine the product and inform the American Red Cross in Tucson, Az by faxing accompanying notification form. The ARC will communicate what further action is to be taken.

4. If the implicated product is not in the Blood Bank inventory personnel shall reach all administration logs to locate the product.

5. If the implicated product has been provided to a recipients Blood Bank personnel shall obtain the name of the recipient, the date the product was provided to the patient and the name of the ordering/attending physician.

6. The information regarding the implicated product to include the case identification number (provided by ARC), disposition of the product, name of recipient (if product was transfused), date transfused and the recipient’s physician shall be recorded on the Lookback Documentation Form provided by the Red Cross.

7. Once this information is obtained, the partially completed form shall be given to the Laboratory Manager who will then initiate the notification process.

8. Notification will preferably be done through the patients attending/ordering physician. If the physician is unavailable or unwilling to make notification of recipient, this notification will be the responsibility of the Laboratory Manager or designee.

9. Notification shall be given to the recipient or if deceased; a minor or incompetent, the notification shall be given to the recipient’s legal representative. This process must include at least three separate attempts. Each attempt must be documented with the date, manner of notification, result of notification and name of person attempting the notification on the lookback documentation form.

10. If the patient is not readily available at least 3 attempts in one week shall be made to make contact. If both the physician and/or the recipient are not found within an
eight (8) week period the hospital/laboratory is not expected to continue its search. It will be up to the laboratory to decide to extend the number of attempts.

11. If the physician accepts responsibility for notifying the recipient they are not required to inform the lab if notification occurred or not.

12. If the laboratory was informed by the physician that notification did not occur then the responsibility of notification falls on the laboratory. Responsibility is relinquished only after the laboratory has made three attempts to locate/contact the patient in one week during an 8 week period.

13. Once patient has been located/contacted information for testing and counseling shall be given. Information pertaining to fees, identification process, physician request forms or any residency requirements must be provided. The CDC has a national Aids Hotline that can be reached at 1-800-342-2437, 24 hrs/day. The patient may also be referred to the CDH Clinic for further counseling or treatment.


Revised Date: 12/2006, 10/2008, 11/2013, 06/2014
Cochise Regional Hospital
Laboratory Policies

Microbiology Specimens

POLICY

It is the policy of Cochise Regional Hospital Laboratory that all microbiology specimens will be sent to Sierra Vista Regional Health Center (SVRHC) (CLIA#03D06691900). Specimens will be transported once daily via courier. Reports will be faxed to a dedicated fax line upon their release from SVRHCs microbiologist. Specimen collection, transport, and rejection will follow SVRHC policies and procedures. (See SVRHC handbook).

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Unable to Perform In-House

POLICY

Whenever laboratory tests are unable to be performed in-house due to instrument failure, reagent failure, personnel shortages, etc., the tests will be sent to the nearest facility performing the assay (i.e., Copper Queen Hospital, Sierra Vista Regional Health Center). If delay of results is not a factor, the tests will be sent to the reference laboratory used by Cochise Regional Hospital.

PROCEDURE

When a test cannot be done in house, the Medical Technologist Team Leader or Technologist in charge will complete a down time memo form indicating which instrument is affected, what tests, where testing will occur, and who picked it up. All specimens will be logged onto an instrument down time log. Technologist in charge shall call either SVRHC or Copper Queen Hospital for acceptance of specimens. The down time memo will be delivered to patient areas to be signed by the charge nurse. A copy of the memo will be left at the nursing station until instrument is functional. The lab will return a copy for their records. Laboratory technologist/personnel will notify nursing units and C.O.O. when instrumentation is down as well as when it is functional again.

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
Cochise Regional Hospital

LABORATORY INSTRUMENT

DOWNTIME SEND-OUT LOG

(Check off when results are faxed back to Laboratory - initial, date and time received.)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Patient name</th>
<th>Date</th>
<th>Time Collected</th>
<th>Time Picked Up</th>
<th>Courier</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Instrument Preventative Maintenance

POLICY

Laboratory equipment is maintained according to manufacturer’s recommendations. A maintenance log is kept near each major piece of instrumentation as well as in each instrument. Routine daily, weekly, monthly, quarterly, and semi-annual maintenance is performed by the laboratory and logged on these records. Abbott is responsible for providing a maintenance record for each service call to include preventive maintenance updates. These records are kept in each instrument maintenance manual/clipboard.

___________ will perform safety inspections and routine maintenance requiring calibration testing on equipment.

Major pieces of instrumentation will have regular scheduled major preventative maintenance by the manufacturer.

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Daily Surveillance

POLICY

Laboratory reports and logs are reviewed daily by the Laboratory Manager or a designated technologist. A checklist is initialed to document review. Any problems or concerns are written on the Surveillance Problem Log along with action performed. The daily review includes the following:

PATIENT RESULTS

1. Daily reports are checked for appropriate resulting, panic values called, and complete testing.

2. Computerized logs for the Architect C4100, Ruby Cell Dyn, and CA-500 are reviewed for analyte trends and inappropriate results.

3. Computer is checked for incomplete reports in the pending logs under All Pending and Pending Phlebotomy. All test under pending phlebotomy that are 3 days old are cancelled.

QUALITY CONTROL

1. Levy Jennings are reviewed for outliers and trends on Architect C4100, Ruby Cell Dyn, and CA-500.

2. Blood Bank and Urinalysis QC is reviewed and initialed as appropriate.

INSTRUMENTS

1. Communication logs are reviewed for instruments.

2. Maintenance records are reviewed for completeness.

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
### Laboratory Surveillance Maintenance Checklist

**Month:** ___________   **Year:** ___________

<table>
<thead>
<tr>
<th>Day Techs</th>
<th>Counters</th>
<th>Screen</th>
<th>Keyboards</th>
<th>Phones</th>
<th>Centrifuges</th>
<th>Above Cabinets</th>
<th>Night Techs</th>
<th>Refrigerators</th>
<th>Breakroom</th>
<th>Instruments</th>
<th>Sinks</th>
<th>PRBC/Blood Units</th>
<th>Microscope Maint.</th>
<th>Phlebotomists</th>
<th>Pending Log</th>
<th>Fax Log</th>
<th>SV Reports</th>
<th>OP Charts</th>
<th>Weekly Duties</th>
<th>Day Techs</th>
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**Legend:**
- **Day Techs:** Tasks performed by day shifts.
- **Night Techs:** Tasks performed by night shifts.
- **Weekly Duties:** Tasks performed weekly.
- **Monthly Duties:** Tasks performed monthly.
- **Yearly Duties:** Tasks performed yearly.

**Notes:**
- Regular maintenance and cleaning are essential for securing the safety and efficacy of laboratory equipment.
- Ensure all security protocols are followed during maintenance activities.
- Records of all maintenance activities should be documented and preserved for future reference.

**Contact Information:**
- For any discrepancies or urgent issues, contact the technical support team immediately.

**Additional Information:**
- This checklist is a part of Cochise Regional Hospital’s comprehensive quality assurance program.
- Regular review and update of this checklist are essential for maintaining high standards of laboratory operations.

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**Cochise Regional Hospital**

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Cochise Regional Hospital

Laboratory Policies

Quality Control Policy

POLICY

It is the policy of Cochise Regional Hospital Laboratory to follow all current federal, state, and manufacturer’s requirements for quality control for all lab testing.

PROCEDURE

Below is a quality control program for each clinical lab area:

Chemistry — Architect C400

1. Two levels of chemistry control are run each day of use.

2. Standards or calibrations are run as outlined by each procedure. Assays are calibrated as needed by the manufacturer’s recommendations, each new lot number change or as needed per the QC troubleshooting procedure.

3. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Imunochemistry — Architect i1000

1. Two levels of chemistry control are run each day of use.
2. Calibrators are run as outlined by each procedure. Assays are calibrated as needed by the manufacturer’s recommendations, each new lot number change or as needed per the QC troubleshooting procedure.

3. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Hematology - Ruby Cell Dyn

1. Three levels of controls are run every 8 hours on each day of use.

2. Any manual differential that is performed is evaluated by the tech for agreement with the Ruby Cell Dyn results.

3. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Coagulation — CA-500

1. Two levels of IL Coagulation controls are run every 8 hours on each day of use.

2. Participation in a Joint Commission/CM/CAP approved proficiency program.

Sedimentation Rates — Polymedco Sedimat II/Excyte 10

1. Two levels of Polymedco Controls are run on each day of use.

2. Participation in Polymedco Assurance Program.

3. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Urinalysis — Bayer Clinitec Status

1. Two levels of Kova-Trol are run each day of use.

2. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Serology

1. Each test kit has manufactured supplied controls that are run as per manufacturer recommendations.

2. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Blood Bank

1. Ortho’s Confidence System is performed each day of use for gel systems.

2. Participation in a Joint Commission/CLIA/CAP approved proficiency program.
Microbiology

1. Fisher brand gram stain controls are used for each gram stain performed.

2. All manual test kits are QC’d with each lot number change or on the first of each month. Internal control results are documented on each test performed.

3. Participation in a Joint Commission/CLIA/CAP approved proficiency program.

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Quality Control Run Acceptance Criteria

POLICY

It is the policy of Cochise Regional Hospital Laboratory to accept a run of patient test results providing the following quality control criteria is met.

PURPOSE

To provide technologist with guidelines for accepting control runs.

Run Acceptance Criteria for Chemistry, Hematology, and Coagulation

Three Controls in Use

Accept the run unless:

1. One control is greater than 3 S.D. from the mean.
2. Two of the controls are greater than 2 S.D, but less than 3 S.D from the mean.
3. One control is greater than 2 but less than 3 S.D from the mean on two successive runs.
4. Patient results appear unlikely, regardless of control results.

Two Controls in Use

Accept the run unless:

1. One control is greater than 3 S.D. from the mean.
2. Both controls are greater than 2 S.D, but less than 3 S.D from the mean.
3. One control is greater than 2 but less than 3 S.D from the mean on two successive runs.
4. Patient results appear unlikely, regardless of control results.

One Control in. Use

Accept the run unless:
1. Control value exceeds 2 S.D from the mean.

2. Patient results appear unlikely, regardless of control results.

For Urinalysis, Serology, Blood Bank, and Microbiology, controls must be correct or the run must be rejected.
Cochise Regional Hospital

Laboratory Policies

Quality Control Troubleshooting Protocol for QC Out of Control POLICY

It is the policy of the Cochise Regional Hospital Laboratory that quality control programs exist in all laboratory areas. When Quality Control values fall outside the established limits, the following steps are to be followed:

1. Do not report patient results.
2. Review procedures and analytic system for identifiable errors.
3. Pour or reconstitute fresh control(s). Run both prior control(s) and fresh control(s).
   a) If fresh control(s) is/are within limits, repeat the patient run and report. Include a fresh control with the repeat patient run.
   b) If fresh control(s) and repeat control(s) remain unacceptable, make or change reagent.
4. Rerun control(s) using new reagent.
   a) If control(s) is/are now within limits, repeat patient run (including a control) and report results.
   b) If control(s) remain unacceptable, troubleshoot procedure or instrument in conjunction with the primary operator, hotline personnel, or lab manager.
5. Discard any control material/reagents which yield unacceptable results.
6. Do not report any patient results until you have an acceptable control run.
7. Document all action taken in the communication log. Explain all action taken in QC tile in instrument. If no computerized log exists, then explain action taken in communication log.

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
Cochise Regional Hospital
Laboratory Policies

Record Retention

POLICY

It is the policy of the Cochise Regional Hospital Laboratory to keep all records in accordance to the following schedule and Joint Commission and CMS standards.

Clinical Pathology

<table>
<thead>
<tr>
<th>Record Type</th>
<th>Retention Period</th>
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<tbody>
<tr>
<td>Test Requisitions</td>
<td>2 years</td>
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<tr>
<td>Log Books</td>
<td>2 years</td>
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<tr>
<td>Quality Control Records</td>
<td>2 years</td>
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<tr>
<td>Equipment Records</td>
<td>2 years for performance</td>
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<td>(for life of equipment for major repairs and annual maintenance)</td>
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<tr>
<td>Proficiency Testing</td>
<td>2 years</td>
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<tr>
<td>Instrument Printouts</td>
<td>2 years</td>
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<tr>
<td>Discontinued Procedures/Policies</td>
<td>2 years</td>
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<tr>
<td>Blood Samples</td>
<td>7 days</td>
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<tr>
<td>Urine Samples</td>
<td>24 hours</td>
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<tr>
<td>Blood Smears</td>
<td>2 months</td>
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Blood Bank

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<thead>
<tr>
<th>Record Type</th>
<th>Retention Period</th>
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<tbody>
<tr>
<td>Testing Records</td>
<td>5 years</td>
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<tr>
<td>Reports</td>
<td>5 years</td>
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<tr>
<td>Quality Control</td>
<td>5 years</td>
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<tr>
<td>Donor/Recipient Records</td>
<td>Indefinitely</td>
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<tr>
<td>Histology/Cytology</td>
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</table>
Pathology Reports 10 years


Effective: 5/09

Reviewed: 12/13

Revised: 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Precision PCX Glucose Meter (Abbott)

POLICY

It is the policy of the Cochise Regional Hospital Laboratory to provide point of care testing services according to Joint Commission and CMS standards and guidelines.

PRINCIPLE

The Precision PCX has been developed to allow rapid measurement of blood glucose (D-glucose) by using electrochemical detection technique. This bio-sensor system employs a disposable dry reagent strip technology, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (Aspergillus niger). When a blood drop is applied to the target area of the test strip, the glucose oxidase catalyses the oxidation of glucose in the drop to produce gluconic acid. During the reaction, electrons are transferred by an electrochemical mediator to the electrode surface. This will generate a current that is measured by the system. The size of the current generated is proportional to the amount of glucose present in the blood drop and will give an accurate reading of the blood glucose concentration.

MATERIALS

1. Precision PCX Monitor as supplied in the laboratory and at various locations throughout the hospital. PCX monitors are stored in the supplied carrying cases. Maintenance and troubleshooting procedures are not intended as part of this procedure and may be found in the Precision PCX Operator’s Manual.

2. Precision PCX Blood Glucose test strips as supplied in the laboratory. Each test strip is sealed in individual Coil packets. The test strips are stable until the expiration date printed on the bar code label when stored between 4degreesC and 30 degreesC. The bar code label contains the lot number of the test strip as well as the expiration date, control solution ranges and lot specific calibration information. After opening the foil packet, each test strip should be used promptly. Do not handle the test strip with wet or dirty hands. Keep the strips out of direct sunlight.

3. Lancets for obtaining a blood sample.
4. Alcohol pads for disinfecting the punctured area.
5. Sterile gauze pads.

SPECIMEN

The specimen of choice for this test is fresh whole blood obtained by approved laboratory methods. Collection of such specimens will be a part of the general procedure for this test.

NOTE: Venous or arterial blood may be tested provided the sample is used within 30 minutes of collection. Caution should be taken to clear the arterial line before blood is drawn and applied to the test strip. Sodium heparin, lithium heparin or EDTA must be used as an anticoagulant. Do not use collection tubes that contain fluoride or oxalate because they may interfere with the test.

Quality Control:

External Low Level and High Level quality control material is supplied for quality control testing of the Precision PCX. Quality Control material is tested once each 24 hours and must produce acceptable results before patient testing can be performed. Unopened control material is stable until the expiration date printed on the vial label. Opened control material is stable for 90 days after opening when stored between 4 degrees and 30 degrees C. As an added feature of the Precision PCX, operators are “locked out” from using the monitor until acceptable quality control results are obtained. Also, the Precision PCX monitor will not accept control solution that have passed their expiration date.

Procedure:

1. Press ON/OFF to turn on the monitor.
2. Press “2” to select CONTROL TEST.
3. Manually enter the Operator ID via the keypad, then press ENTER.
4. Scan or manually enter the low control solution lot number via the keypad, then press ENTER.

NOTE: If UNEXPECTED LEVEL screen appears, the operator may either:
1. Enter 1 to ReEnter the expected level, or
2. Enter 2 to continue to test the unexpected level.
5. Scan the test strip lot number and press ENTER.

6. Open the foil test strip packet at the notch and tear up or down to remove the test.

7. The monitor beeps when the sample is accepted and the SAMPLE ACCEPTED screen appears. Recap the control solution vial tightly.

8. Wait for the monitor to analyze the control solution and display the test result.

9. Note that the result either passes or fails.

10. Remove the test strip from the monitor when finished testing.

11. Select and Press 1 to test the next level of control.

12. After successful testing of the control material. Press MENU to return to the MENU mode or Press ON/OFF to turn off the monitor.

Remedial Action:

In the event that quality control testing produces unacceptable results as indicated by the displayed fail message as it appears on the monitor display, the following remedial action procedure is offered.

1. Retest the quality control material insuring that all steps in the procedure are carefully followed.

2. Insure that the test strips and/or quality control material have not exceeded their expiration dates.

3. Obtain a new lot number of test strips and retest the quality control material.

4. Obtain a new vial of quality control material and retest. Insure that the solution has been well mixed before proceeding with testing.

5. Contact the Laboratory Manager.

Procedure

Obtaining a Capillary Blood Sample:

1. Choose the lateral surface of the ring finger as a site for the capillary puncture. Other fingers may be used; however, the surface chosen should be free of callous, hematoma, burns, or scar tissue.
2. Disinfect the chosen area with an alcohol swab. Soap and water may be used to disinfect the area if multiple punctures are needed to prevent the drying and cracking of the skin layer.

3. The puncture site may be allowed to air dry or a sterile gauze pad may be used.

4. Remove the circular top of the supplied lancets to expose the needle. Do not touch the needle end.

5. Using the needle end of the lancet, puncture the disinfected area of the finger. The puncture should provide a drop of blood at the site without squeezing the finger excessively.

6. Wipe the first drop of blood with a sterile gauze pad to remove any left over alcohol or cleansing agent and any tissue fixed.

7. The finger may be gently "milked" by gently squeezing down the finger towards the puncture site until a hanging drop of blood is obtained. Avoid aggressive squeezing of the finger.

Glucose Monitor procedure:

1. Press ON/OFF to turn on the monitor.
2. Press "1" to select PATIENT TEST.
3. Manually enter the OPERATOR ID via the keypad, and then press ENTER.
4. Manually enter the PATIENT ID via the keypad, and then press ENTER.
5. Press SCAN to scan the test strip bar code and press ENTER.
6. Open the foil strip packet at the notch and tear up or down to remove the test strip.
7. With the contact bars facing up, insert the test strip into the test strip port until it stops.
8. Apply a drop of blood directly from the patient’s finger (as obtained by the above puncture) to the target area on the test strip.

9. The monitor beeps when the sample is accepted and the SAMPLE ACCEPTED screen appears. If the test fails to start, a second drop of blood may be applied to the target area within 30 seconds of the first blood drop. If the test fails to start after the
second drop is applied or if more than 30 seconds have passed, discard the test strip and repeat the test.

10. Wait for the monitor to analyze the sample and display the test result.

11. Test results are displayed on the monitor screen after 20 seconds.

12. Remove the test strip from the monitor when finishing testing.

13. The operator then has the choice of performing a new test, or repeating the previous test or recalling the patient’s history.

Limitations:

1. The Precision PCX test strips are designed for use with fresh whole blood samples. Do not use serum or plasma samples.

2. The Precision PCX test strips are designed for use between 15 degrees and 40 degrees C and between 10% and 90% relatively humidity.

3. Altitudes up to 2,195 meters above sea level do not affect results obtained with the Precision PCX analyzer.

4. No significant effect was found for hematoerits between 20% and 70%. Hematocrits below 20% may cause higher results, while hematoerits above 70% may cause lower results.

5. High levels of acetaminophen (up to 100 ug/ml) will not affect results.

6. The system has been evaluated with neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonatal glucose values below 50 mg/dl.

7. Test results may be erroneously low, if the patient is severely dehydrated or severely hypotensive, in shock, or in a hyperglycemic-hypersomolar state (with or without ketosis).

Interpretation of Test Results:

At the end of the 20 second incubation time, the glucose value for the sample is displayed. Blood glucose results that are above or below the action range for the monitor are displayed with an accompanying triangle indicated results that require notification of the attending physician.

Expected Results:
Normal fasting values for adult patients that are non-diabetic or not pregnant are: 70 to 110 mg/dl

Two hours after 75g of glucose, the normal values for adult non-diabetic or non pregnant patient is: <140 mg/dl

Reporting of Patient Results:

Patient glucose values are reported in the LIDS as the numerical value obtained from testing. Values under 50 ng/dl and over 400 mg/dl must be repeated. All repeated tests MUST be checked by the laboratory.

Linearity of Test System:

The Precision PCX will read results as low as 20 mg/dl and as high as 600 mg/dl. A message will appear stating that the value is beyond the instruments capability. Each sample MUST be rechecked by the laboratory.

Inoperable Test System:

In the event that the Precision PCX is unavailable for testing, the laboratory will perform the test using the supplied chemistry analyzer.

Clinical Significance:

The benefit of whole blood glucose testing as a point of care procedure is well documented for the treatment of and monitoring of blood glucose values from diabetic patients.

Qualified Personnel/Training:

Persons qualified to be trained on Precision PCX Blood Glucose System are nursing staff C.N.A., M.A., R.N. R.R.T.), laboratory staff (i.e., phlebotomist, laboratory assistants. Medical Laboratory Technician, Medical Laboratory Technologist). Training and troubleshooting is provided the laboratory. Training is provided for eligible employees upon employment. Recertification for trained personnel will be yearly upon original training date.

References:

Precision PCX Blood Glucose Test Strips insert, 3/01, Abbott Laboratories, MediSense Products, Bedford, MA

Precision PCX Point of Care, Healthcare Professional Operator's Manual, 3/30, Abbott Laboratories, MediSense Products, Bedford, MA
COCHISE REGIONAL HOSPITAL

Chemical Hygiene Plan

CHEMICAL HYGIENE PLAN

The Laboratory Department of Cochise Regional Hospital (CRH) is committed to proving a safe working environment and believes employees have a right to know about health hazards associated with their work so that employees can make knowledgeable decisions about any personal risks of employment. This Chemical Hygiene Plan includes policies, procedures, and responsibilities designed to develop in employees an awareness of potentially hazardous chemicals in the work place and to train employees in appropriate, safe working conditions.

Cochise Regional Hospital (CRH) feels it is important as an employer to assume responsibility for laboratory safety. All employees will have access to pertinent safety information through their laboratory supervisory staff. The people who work in our laboratory are best able to detect potential hazards in either our facility or in the work procedures. When safety concerns arise, inform the employee how best to handle hazardous chemicals and how to make use of the Chemical Hygiene Plan.

Laboratory Manager

Veronica L Santiago,

Max Mirot, Pathologist

Effective: 5/09

Reviewed: 12/13

Revised: 12/13, 06/14
GLOSSARY

The following terms are used as part of the Chemical Hygiene Program:

ACUTE: An adverse effect with symptoms of high severity coming quickly to a crisis.

CARCINOGEN: A substance capable of causing cancer.

CHEMICAL AGENTS: A wide variety of fluids that have a high potential for body entry by various means. Some are more toxic than others and require special measures of control for safety and environmental reasons.

CRONIC: adverse effects with symptoms that develop slowly over a long period of time or that frequently recur.

COMBUSTIBLE: Able to catch on fire and burn.

DOT: Department of Transportation

EPA: Environmental Protection Agency

FLAMMABLE: Capable of being easily ignited and of burning with extreme rapidity.

INFECTIOUS AGENTS: Sources that cause infections either by inhalation, ingestion, or direct contact with the host material.

LABORATORY SCALE: Work with chemicals that can easily and safely be manipulated by one person excluding the commercial production of chemicals for sale.

LABORATORY USE: A workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

LC 50: The concentration of a substance in air that causes death of 50% of the animals exposed by inhalation. A measure of acute toxicity.

LD 50: The dose that causes death in 50% of the animals exposed by swallowing a substance. A measure of acute toxicity.

MSDS: Material Safety Data Sheets

MUTAGEN: Capable of changing cells in such a way that future cell generation is affected. Mutagenic substances are usually considered suspect carcinogens.
OSHA: Occupational Safety and Health Administration, the regulatory branch of the Department of Labor concerned with employee safety and health

PEL: Permissible Exposure Limit. This is the legally allowed concentration in the workplace that is considered a safe level of exposure for an 8-hour shift, 40 hours per week.

PH (pH) A measure of how acidic or caustic a substance is on a scale of 1 to 14. A pH of 1 indicates that a substance is acidic; a pH of 14 indicates that a substance is basic.

PHYSICAL AGENTS: Workplace sources recognized for their potential effects on the body. Heat exposure or excessive noise levels are examples of this risk group.

SENSITIZERS: Agents to repeated exposure over time creating an allergic reaction at some point in time.

STERILITY: Changes made in male or female reproductive systems resulting in inability to reproduce.

TERATOGENS: A substance that causes a deformity in newborns if a significant exposure exists during pregnancy.

TLV: Threshold Limit Value. The amount of exposure allowable for an employee in an 8-hour day.
ENGINEERING CONTROLS

CRH laboratory handles very small quantities of toxic chemicals; therefore we do not have a fume hood.

Eyewash fountains are inspected annually.

Fire extinguishers are inspected annually by United Fire Equipment Co (telephone 602-622-3639). Additionally, CRH’s maintenance department inspects the fire extinguishers on a monthly basis.

Airflow through the microbiology room is exhausted to the exterior of the building. The remainder of the laboratory work area has 50% of its airflow recirculated.

All chemical hygiene-related equipment is monitored continuously and modified if inadequate.

PERSONAL PROTECTIVE EQUIPMENT

Employees are required to wear gloves when the employee has the potential for direct skin contact with blood, hazardous chemicals, and infectious materials.

Lab coats are to be worn in the lab work area or during patient contact and are to be worn over the employee’s clothing. Lab coats are provided by CRH.

All lab coats are removed prior to leaving the laboratory and either placed on the appropriate rack or discarded. All lab coats are to be placed in the appropriate hamper when visibly contaminated.

Masks and eye protection or chin-length face shields are worn to prevent splashes or sprays of blood, infectious materials, or hazardous chemicals if there is a potential for nose, or mouth contamination. This equipment is located in the supply closet in microbiology.

Where the use of respirators is necessary to maintain exposure below permissible exposure limits, CRH provides these at no cost to employee. The respirators shall be elected and used in accordance with the requirement of 29 CFR 1910.134,

CONTAMINATED WASTE REMOVAL/DISPOSAL

Waste laboratory chemical disposal is done in a manner to assure that minimal harm to people, other organisms, and the environment will result.

Certain chemicals are permissible for drain disposal. Only those chemicals reasonable soluble in water are suitable for drain disposal. A compound is
considered water soluble if it dissolves to the extent of at least 3%. These compounds are flushed with at least 100 volumes of excess water. Some exceptions should be noted.

Those organics with boiling points less than 50° C

Those hydocarbons, halogenated hydrocarbons, nitro compounds, mercaptains, and most oxygenated compounds that contain more than five carbon atoms (e.g., freon)

Those organics that are explosives such as azides and peroxides

Concentrated acids or bases

Highly toxic malodorous or lachrymatory substances.

**ADMINISTRATIVE CONTROLS**

The laboratory manager is responsible for the safe operation of the area. All activities and procedures require approval by the medical director and the laboratory manager before implementation. Appendix F lists the important telephone numbers for the laboratory.

Environment monitoring is required in all laboratories for the following chemicals stored or used 3 times/week:

FR 1910 Subpart Z

1910.1001 Asbestos, tremolite, anthophyllite, and actinolite (elf 7/21/86)
1910.1002 Coal tar pitch volatiles; interpretation of term
1910.1003 4-Nitro biphenyl
1910.1004 alpha-Naphthylamine
1910.1005 [Reserved]
1910.1006 Methyl chloromethyl ether
1910.1007 3, 3” -Dichlorobenzidine (and its salts)
1910 1008 bis-Chloromethyl ether
1910.1009 beta-Naphthylamine
1910.1010 Benzidine
<table>
<thead>
<tr>
<th>Code</th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1910.1011</td>
<td>4-Aminodiphenyl</td>
</tr>
<tr>
<td>1910.1012</td>
<td>Ethylebeunube</td>
</tr>
<tr>
<td>1910.1013</td>
<td>Beta-Propiolactone</td>
</tr>
<tr>
<td>1910.1014</td>
<td>2-Acetylaminofluorene</td>
</tr>
<tr>
<td>1910.1015</td>
<td>4-Dimethylaminoazobenzene</td>
</tr>
<tr>
<td>1910.1016</td>
<td>N-Nitrosodimethylamine</td>
</tr>
<tr>
<td>1910.1017</td>
<td>Vinyl chloride</td>
</tr>
<tr>
<td>1910.1018</td>
<td>Inorganic arsenic</td>
</tr>
<tr>
<td>1910.1025</td>
<td>Lead</td>
</tr>
<tr>
<td>1910.1028</td>
<td>Benzene</td>
</tr>
<tr>
<td>1910.1029</td>
<td>Coke over emissions</td>
</tr>
<tr>
<td>1910.1043</td>
<td>Cotton dust</td>
</tr>
<tr>
<td>1910.1044</td>
<td>1,2-dibromo-3-chloropropane</td>
</tr>
<tr>
<td>1910.1045</td>
<td>Acrylonitrile</td>
</tr>
<tr>
<td>1910.1047</td>
<td>Ethylene oxide</td>
</tr>
<tr>
<td>1910.1048</td>
<td>Formaldehyde</td>
</tr>
<tr>
<td>1910.1101</td>
<td>Asbestos</td>
</tr>
</tbody>
</table>

Chemical spills are contained using the Think C.L.E.A.N. Plan:

- Contain the spill
- Leave the area
- Emergency: eye wash, shower, medical care
- Notify supervisor

All spills are contained according to OSHA guidelines, using appropriate spill kits.

The Laboratory Manager or Chemical Hygiene Officer makes assessment of significant risk of all operations. Chemical hygiene and safety policies will be
established for each task performed and engineering controls of personal protective equipment assigned.

MEDICAL CONSULTATIONS AND EXAMINATIONS

All employees needing medical attention are referred to the CRH emergency room (phone ext. 5808).

All medical examinations and consultations are performed by or under the direct supervision of a licensed physician without cost to the employee, without loss of pay, and at a reasonable time and place.

The employee is sent for medical evaluation:

Whenever signs and symptoms associated with a hazardous chemical develop.

When environmental monitoring reveals an exposure level routinely above the action levels.

Whenever an event takes place in the work area such as a spill, leak, or explosion resulting in hazardous chemical exposure.

The laboratory provides the following information to the physician:

Identity of the hazardous chemical(s) to which the employee may have been exposed.

A description of the conditions under which the exposure occurred - including quantitative exposure data (if available)

A description of the signs and symptoms of exposure

A copy of the MSDS for the chemicals

The physician provides a written opinion that will not reveal any specific finding of diagnosis unrelated to the exposure but will include:

1. Any recommendation for further medical follow-up

2. Results of the medical examination and any associated tests

3. Any medical condition that may be revealed in the course of the examination that may place the employee at increased risk as a result of exposure to a hazardous chemical found in the workplace
4. A statement by the physician that the employee has been informed of the consultation/examination results and any medical condition that may require further examination or treatment.

CHEMICAL HYGIENE OFFICER/COMMITTEE

The chemical hygiene responsibilities rest with the Chemical Hygiene Officer who is appointed by the Chief Executive Officer must:

Work with administrator and other employees to develop and implement appropriate chemical hygiene policies and practices

Certify the performance of protective equipment

Monitor procurement, use and disposal of chemical used in lab

See that appropriate audits are maintained

Know the current legal requirements concerning regulated substances

Seeks ways to improve the chemical hygiene program.

The immediate supervisor has overall responsibility to

Ensure that workers know and follow the chemical hygiene rules, that protective equipment is available and in working order, and that appropriate training has been provided.

Provide regular, formal chemical hygiene and housekeeping inspections including routine inspections of emergency equipment.

Know the current local requirements concerning regulated substances,

Determine the required levels of protective apparel and equipment.

Ensure that facilities and training for use of any material being ordered are adequate.

The laboratory employee is responsible for:

Planning and conducting each operation in accordance with the institutional chemical hygiene procedures

Developing good personal chemical hygiene habits.

Safety and chemical hygiene issues will be discussed at lab staff meetings.
a) of MSDS
b) MSDS information if not currently
c) Labeling information

Hazard warnings
El Carcinogen warnings

Location in workplace

Procedures for handling hazardous chemicals
a) Work practices
b) Proper moving, storing, and use
c) PEL for specific chemicals used by the employee
d) Visual appearance of chemicals used by the employee
e) Environmental monitoring required
f) Signs and symptoms of exposure
g) List of Target Organ Poster
h) Protective equipment used to prevent overexposure
i) Conditions to avoid

Environmental protection
a) Emergency procedures
b) Spill containment (Think C.L.E.A.N. protocol)
c) Medical consultation procedures

Documentation of initial: and annual training

**HOUSEKEEPING**

Floors are cleaned regularly by housekeeping. All employees of the housekeeping department are formally trained in the risks associated with working in the laboratory. The Education Coordinator relay this information to housekeeping employees.
The plant operations personnel conduct a quarterly inspection of the lab areas to assess whether:

Floors and aisle ways are free of obstruction

Waste is deposited in appropriate receptacles and properly removed from the laboratory

Chemical spills are cleaned according to established protocol

Proper storage is accomplished to minimize clutter

**RECORD KEEPING**

The laboratory has established and maintained an accurate record for each employee of environmental monitoring, medical consultations, and examinations, including tests or written opinion required.

Accident records are written and retained by CRH Risk Manager and Employee Health Coordinator

Chemical Hygiene Officer maintains inventory and usage records for high-risk substances.

Safety Officer maintains environmental monitoring records.

Education Coordinator maintains medical consultation records.

All records are kept, transferred, and made available in accordance with 29 CFR 1910.20.

**APPENDICES:**

a. DOT Hazard Classification List

b. EPA Hazard Classification List

c. Chemical Inventory Form

d. Sample MSDS Request Form

e. MSDS Example

f. Directory

g. Target Organ List
APPENDIX A:

DOT HAZARD CLASSIFICATION LIST Hazard Classification Example

1. Explosive A & B Dynamite
2. Explosive C Fireworks
3. Blasting agents Plastic explosives
4. Radioactive materials CO-60 or 1-130
5. Flammable liquids Alcohol
6. Pyrophoric liquids Phosphorus hydrides
7. Non-flammable compressed gases Nitrogen
8. Flammable gases Oxygen
9. Combustible liquids Kerosene
10. Flammable solids Picric Acid/10%/wet
11. Oxidizer Nitric acid
12. Corrosive material Hydrochloric acid
13. Irritating material Lacramator
14. Poison A Heptachlor
15. Poison B Phenol
16. Organic Peroxide Benzoyl Peroxide
17. *ORM-A Formaldehyde
18. ORM-B Mercury
19. ORM-c Asbestos
20. ORM D Bleach
21. ORM-E Ferric sulfate
22. Etiological agents Microorganisms (E. coli)

*ORM=Other Regulated Material
APPENDIX B

EPA HAZARD CLASSIFICATION LIST

IGNITABLE WASTE: Flash point<140 degrees F
Flammable Solids (910)
Oxidizers (11)
Flammable Gases (8)
Some combustible liquids (9)
Flammable liquids (5)
Pyrophoric liquids (6)

CORROSIVES: Any liquid of pH 2 or 12.5 (12)

REACTIVE:
Explosives A, B, or C (1, 2, or 3)
Water reactive
Cyanide or sulfide
Organic peroxides
Poison B

EXTRACTION PROCEDURE (EP) TOXIC:

8 metals:
Arsenic
Cadmium
Chromium
Mercury
Silver
Lead
Beryllium Thallium

4 pesticides:
Lindane
Endrin
Toxaphene
Methoxychlor
2 herbicides:
2, 4 D
3, 4 5 T

**APPENDIX B (con’t)**

Poison A and some Poison B (14 and 15)
Irritating material (13)
Radioactive material (4)
ORM-A-B-C (17, 18 and 19)
ORM-E (21)

Note: Numerals in parenthesis indicate chemical categories on the DOT list.
APPENDIX C

CHEMICAL INVENTORY LIST

The chemical inventory list is found at the beginning of each section of the MSDS manual.
APPENDIX E

MSDS Example

ANY COMPANY ANY COMPANY

Material Safety Data Sheet PO BOX 1234

Issued Date: August 1, 1990 ANYTOWN, USA

Section 1: General Information

PRODUCT/CHEMICAL NAME 10% Neutral Buffered Formalin, v/v

Chemical Family

Aldehyde

Business Telephone (314)555-1235

Section II: Hazardous Ingredients & TLV

Accrediting Agency

3% Formaldehyde 10v/v 1ppm TWA

OSHA

Stabilized with methanol 2ppm STEL

OSHA

(11% V/V) probable carcinogen)

METHANOL 1 200PPM

SECTION III: Physical Data

Appearance Clear odorless liquid

Odor Pungent odor

Boiling Point (F) 204degrees to 211degrees F

Evaporation rate (Butyl Acetate=1) 0.43
Percent Volatile by Vol. 98%
Solubility in Water 100%-Complete
Specific Gravity (Water-1) 1.109 @ 21degrees C
Vapor Density (Air-I) 1.1
Vapor Pressure (mm of Hg) 19
Section IV – FIRE AND EXPLOSION HAZARD DATA

FLASH POINT

(METHOD USED: pensky-MARTENS): None observed below 180degrees F. (82degrees C)
APPENDIX E (con’t)

FLAMMABLE LIMITS IN AIR, % BY VOLUME:

EXTINGUISHER MEDIA: Alcohol foam, dry chemical, carbon dioxide, and water spray.

UNUSUAL FIRE AND EXPLOSION HAZARDS: May generate formaldehyde gas.

FIRE FIGHTING PROCEDURES: Cooling container with water spray or fog will help to absorb escaping fumes. Evacuate affected areas. Stay upwind and avoid contact with smoke and fumes. If contact cannot be avoided, wear personal protective equipment including chemical splash goggles and air mask with breathing air supply. Runoff from fire control may cause pollution.

SECTION V: REACTIVITY DATA

STABILITY: Stable

INCOMPATIBILITY: Reaction with phenol, strong acids or alkalis may be violent. Formaldehyde and hydrochloric acid may form bischloramethyl ether, an OSHA regulated carcinogen.

HAZARDOUS DECOMPOSITION: Occurs slowly at elevated temperatures, releasing formaldehyde gas.

HAZARDOUS POLYMERIZATION: None

SECTION VI. HEALTH DATA

INHALATION May cause sore throat, coughing, and shortness of breath. Causes irritation to the respiratory tract: May be fatal in high concentrations.
APPENDIX E (Con’t)

INGESTION: Can cause severe abdominal pain, violent vomiting, headaches, and diarrhea. Larger doses may produce decreased body temperature, pain in the digestive tract, shallow respiration, week irregular pulse, unconsciousness and death. Methanol component affects the optic nerve and may cause blindness.

SKIN CONTACT: TOXIC: May cause irritation to skin with redness, pain, and possible burns. Skin absorption may occur with symptoms paralleling those from ingestion.

EYE CONTACT: Vapor causes irritation to the eyes with redness, pain and blurred vision. Higher concentrations or splashes may cause irreversible eye damage.

FIRST AID PROCEDURES

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

INGESTION: If swallowed, induce vomiting immediately by giving two glasses of water and sticking finger down throat. Never give anything by mouth to an unconscious person. Call physician immediately.

SKIN CONTACT: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.

EYE CONTACT: Wash eyes with plenty of water for at least 1.5 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
APPENDIX E (Con’t)

SPECIAL PROTECTION:

VENTILATION: Ventilation adequate to keep formaldehyde concentrations below indicated exposure limits should be provided. If limits may be exceeded, use a full-face air purifying respirator with cartridges approved for formaldehyde (up to 500 ppm) or supplied air respirator.

PERSONAL PROTECTIVE EQUIPMENT: Use chemical splash goggles, neoprene, or polyvinyl chloride gloves and coveralls with long sleeves. Use breathing air supply from airline mask or self-contained breathing mask if exposure limits are exceeded.

SPILL PROCEDURES:

STEPS TO TAKE IN CASE OF RELEASE OR SKILL: Keep upwind of leak, evacuate area until gas gas has dispersed. Soak up small leaks with rags or other absorbent and remove in covered metal containers or drums. Dike large spills. May be neutralized with dilute (5%) solutions of ammonia sodium sulfite or sodium bisulfate and removed. Flush spill area with plenty of water.

WASTE DISPOSAL METHOD: Comply with federal, state, and local regulations. If approved, flush to chemical sewer, incinerate, dispose in hazardous material landfill, or flush to wastewater treatment system. Very dilute solutions can be handled by biochemical action in formaldehyde-adapted waste treatment systems; water spray or fog will help absorb escaping fumes.

SHIPPING INFORMATION:

STORAGE CONDITIONS: Keep container closed. Keep away from heat and open flame, Do not store below 15 degrees C (59 degrees F).
APPENDIX E (Con’t)

SHIPPING CONTAINERS: DOT Shipping Name-Formaldehyde or Formalin Solution. DOT Hazard Class ORM-A (in containers of 110 gallons or Less).

TRANSPORTATION: Keep container dosed. Keep away from heat and open flame. Do not store below 15 degrees C. (59 degrees F).

STORAGE CONDITIONS: DOT Shipping Name: Formaldehyde or Formalin Solution. DT Hazard Class ORM-A (in containers of 110 gallons or less).

TRANSPORTATION: Drums, cubitainers, bottles.
Cochise Regional Hospital

Laboratory Policies

Standing Order

POLICY

In order to be consistent with Medicare reimbursement it is the policy of this laboratory for standing orders to be valid for a period of 3 months, unless otherwise ordered by the primary care physician.

Standing orders must have the following information provided on a prescription or laboratory requisition:

Patient Name

Diagnosis codes

Tests to be performed

Frequency

Physician Signature

Physician’s mailing address and/or fax number

When received in the laboratory the requisition will be scanned to an internal laboratory Standing Order file.

Effective: 5/09

Reviewed: 12/13

Revised: 12/13, 06/14
Form not longer in use

Cochise Regional Hospital

ROUTE I - BOX 30 - TELEPHONE 520/364-7931 TDD ACCESSIBLE
DOUGLAS, ARIZONA 85607
FAX: 520/364-2551

LABORATORY

STANDING ORDER

Date:

Patient Name:

Patient ID Number:

DOB: Diagnosis:

Test(s) Ordered and Frequency:

Physician:

Address:

Phone:

Fax:

Special Instructions:
Cochise Regional Hospital

Laboratory Policies

Infection Control General Policies

POLICY

In accordance with established infection control protocol, the following policies in the laboratory shall be followed:

Standard Precautions will be observed at all times

Smoking is prohibited in the laboratory

Eating or drinking is absolutely prohibited in the laboratory

Food is not to be stored in the laboratory

All personnel will follow good hand washing technique at all times and with particular attention to:

After handling specimens

After personal hygiene functions, i.e., use of restrooms, blowing nose, etc.

Before and after meals

Before patient contact

After removal of gloves

Between each patient contact

All bench areas and work surfaces will be cleaned daily utilizing a 10% bleach solution that will be mixed fresh daily.

PURPOSE:

To provide general guidelines for Infection Control practices in the laboratory setting.

Effective: 5/09

Reviewed: 12/13

Revised: 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Handling of Sharps

POLICY

It is the policy of the Laboratory at Cochise Regional Hospital to follow guidelines developed to protect all personnel from injury and exposure to blood borne pathogens when handling or disposing of contaminated needles, syringes and other potentially infectious material.

POLICY

All phlebotomy trays will be cleaned daily and restocked. All supplies will be moved on a weekly basis and the tray will be wiped down with a 10% bleach solution.

All sharps will be placed in puncture resistant containers on the phlebotomy tray or in the needle boxes located in the laboratory area. Needles will not be recapped, broken or bent prior to disposal. The use of needle safety equipment is highly encouraged.

Used syringes (without attached sharp) can be disposed of in red biohazard bags. If the sharp remains attached, the syringe must he placed in a puncture resistant needle counter.

When the needle container is 3/4, it will be sealed according to manufacturer’s instructions, and sent to environmental services to be incinerated. Sharps containers will not be opened to transfer contents to a different container.

All employee injuries resulting in potential blood borne pathogen exposure will be handled according to policies and procedures outlined in the Exposure Control Plan. An occurrence report and a blood borne pathogen report will be filled out for each such occurrence. Each employee will be made aware of these policies during department-specific orientation.

Effective: 5/09

Reviewed: 12/13

Revised: 12/13, 06/14
Cochise Regional Hospital

Laboratory Policies

Handling of Specimens

POLICY:

It is the policy of Cochise Regional Hospital to provide guidelines in the laboratory setting so as to prevent exposure of employees to blood borne pathogens or other potential infectious disease while handling specimens.

General

1. Mouth pipetting is prohibited. If a specimen must be pipetted, a pipette bulb will be used.

2. Gloves are to be worn when drawing specimens.

3. Gloves will be worn when processing blood or body fluid specimens.

4. Gloves will be removed and hands washed when finished processing specimens.

5. Work surfaces are to be cleaned with a 10% bleach solution daily.

6. Spills of blood or other potentially contaminated fluids will be cleaned with a 10% bleach solution and materials used will be disposed of in a biohazard waste container.

7. Any employee who experiences a blood borne pathogen exposure will report immediately to the Supervisor and will follow guidelines and policies outlined in the Exposure Control Plan.

Specimen Collection

1. Standard Precautions must be adhered to when obtaining, handling, or processing ALL blood/body fluids specimen or other potentially infectious materials. Personal protective equipment shall be utilized as defined in the Exposure Control Plan.

2. During transportation, specimens shall be placed in a biohazard container clearly marked as such.

Opening Specimen/Transfer of Specimen

1. The cork of vacuum containers will not be “popped off”. This action generates aerosols and can become a prime source for the transmission of blood borne disease.
Corks will be twisted off by covering the container with a gauze pad and gently removing the cork. The cork will be disposed of in a biohazard container.

2. Any specimen spillage on containers is hazardous. Care will be taken to avoid all spillage during transfer steps. Any spills that occur should be cleaned with 10% bleach solution, and materials used in clean-up disposed of properly.

Control Sera and Reagents from Biological Sources

1. All material prepared from biological sources are biohazardous in that they are potential agents for the transmission of disease. All such material must be treated as though they were specimens from high risk patients, handled and disposed of as biohazard materials.

Spillage of Biological Samples

1. Spills on paper, or on disposable surfaces, and worksheet, request, or report should be re copied and the original disposed of in a biohazard container.

2. Spills on non-disposable surfaces must be cleaned promptly with an aqueous 1:10 (10%) bleach solution.

Pipetting

1. Mouth pipetting of any substance is prohibited. Disposable pipettes, rubber bulbs, or suitable alternative devices must be used.

2. Bulbs and tubing used for capillary pipetting must be disposed of at regular intervals, in biohazard trash.

3. Pasteur pipettes must be disposed of as biohazard waste.

Storage of Biological Samples

1. All containers with biological samples or reagents in them shall be sealed for covered, or kept in sealed containers unless currently being used.

Pathology Medical Waste Disposal

1. Sections of specimens (tissue, organs, etc.) are placed in 10% Formalin prior to transport from the site where the specimen was obtained. Specimens will then be transported in a container clearly marked as Biohazard to a contracted service for further pathology functions. (See Sierra Vista Pathology Manual for details on transportation and storage)
2. Any specimen that is not sent to pathology will be disposed of as biohazard waste, and sent to be incinerated in a sealed container marked as biohazard waste.

Reviewed: 09/2008, 5/09, 12/13

Revised: 9/08, 5/09, 12/13, 06/14
Cochise Regional Hospital
Laboratory Policies

Blood Bank

POLICY

It is the policy of Cochise Regional Hospital to develop and maintain an ongoing program of infection control as it relates to the performance of blood banking services.

Unit Inspection

Each day all units of blood in the blood bank will be examined for the following:

Hemolysis
Turbidity
Broken Bags
Leaks
Expiration Dates

If any of these things are noted, the unit must be set aside and marked accordingly. The supervisor of the laboratory will be notified and note of the action will be made in the blood bank log.

Culture of Blood Bag

Under no circumstance should a unit of blood be tampered with, with the exception of those units implicated in a transfusion reaction. If such is the case, the following procedure will be followed. Culture of the unit should be done only if a reaction has been noted, and on the order of the patient’s physician, the Medical Laboratory Director, or the Laboratory Director,

Obtain a clean, clear area in which to work
Prep culture bottles according to laboratory protocol
Clean the unused port with iodine and allow to dry for at least 30 seconds

Using a 20 cc disposable syringe and a 16 gauge needle withdraw 15 ml of blood from the bag. If there is less than 15ml of blood remaining in the bag, withdraw 10 ml of culture medium aseptically, inject this into the port, and mix thoroughly with the
remaining contents of the blood. Withdraw the resulting fluid and use to fill the culture bottles. If this is done, make a note of the procedure on the record.

Using 2 culture bottles dispense about 5 ml into each of 3 bottles. Submit bottles with requisition to Microbiology. Label with the patient’s name and accession number, along with the unit number. Note specifically that the specimen is from the bag, not the patient.

Seal the bag, not the patient.

Seal the bag and store at 2-6 degrees C, hold for one (1) week; do not use for infusion.

Observe the three (3) culture bottles for seven (7) days for evidence of bacterial growth under the following conditions:

Anaerobically @ 37 degrees C.

Vented @ 37 degrees C.

Vented @ 25 degrees C


Reviewed: 5/09, 12/13

Revised: 12/13, 06/14
Cochise Regional Hospital
Laboratory Policies

Infection Control: Isolation

POLICY

It is the policy of Cochise Regional Hospital Laboratory to provide a safe working environment for laboratory personnel and patients.

All lab personnel shall follow standard precautions for all patient care.

All lab personnel shall follow isolation techniques established for a specific isolation situation when entering an area where isolation is in effect. Lab coats worn outside for general patient care will be removed and an isolation gown (if required) or a clean patient gown (isolation not requiring the use of gown) will be donned over regular uniform.

All specimens and containers from isolation shall be enclosed in a biohazard bag. The specimen shall be placed in the bag in the room utilizing clean gloves, so as to keep the outside of the bad uncontaminated for transport to the laboratory.

All labels, requisitions, and containers will be clearly marked “ISOLATION” to alert personnel to the potential hazard.

All materials used in the collection of specimens in an isolating setting will be disposed of in the room in the appropriate biohazard trash or sharps container.

Tourniquets used in isolation setting will be left in the room and disposed of after patient discharge. Only those supplies needed to obtain the ordered specimen will be taken into the isolation setting, The phlebotomy tray will be left outside the isolation setting.

All personnel are to follow the hand washing guidelines and hand will be washed after leaving the isolation setting and before transporting the specimen to the laboratory.

Reviewed: 09/2008, 5/09, 12/13

Revised: 9/08, 5/09, 12/13, 06/14
Cochise Regional Hospital
Laboratory Policies

Infection Control: Microbiology

POLICY

It is the policy of Cochise Regional Hospital Laboratory that all personnel will adhere to Standard Precautions when obtaining or working with microbiologic specimens. All personnel will adhere to the policies as outlined in the Exposure Control Plan.

PURPOSE

To provide guidelines in the microbiology laboratory for the provision of services directed toward the diagnosis and treatment of patients, prevent exposure to laboratory personnel and act as an effective liaison to the infection control program of the hospital. The results of microbiology studies are of great importance to the infection control program that provisions are made to effect the centralization of collection of data on:

- Etiology of infection and the results of follow-ups on patients and members of the staff
- Presence of unusual or hazardous microorganisms
- Results of serological, bacteriological, and parasitological examinations of patients and staff

The microbiology service is planned to handle two (2) areas of responsibility:

The microbiological diagnosis of patients and personnel, and:

The implementation of safety measures to prevent the transmission of infection to personnel in the laboratory.

All specimens received shall be identified with the source individual’s name, room number, patient number, source, and the date and time the specimen was obtained. This data must correspond to the order received in the order entry system. Any discrepancies in this information must be resolved before any results can be reported on the patient in question, prior to the specimen being utilized. All specimens will be prepared for transport in containers clearly labeled as a biohazard material.

All specimens, media, and any other contaminated material is to be disposed of in a biohazard waste container lined with double red bag, or in a puncture resistant sharps container, if appropriate.
All work areas will be wiped down daily at the end of the regular working with a solution of 10% bleach.

The lab manager will be responsible for reporting those findings that are required by law to be reported to the public health department within 24 hours (see Attachment A) when IC is not available. All other reportable diseases will be reported to the Infection Control Program for follow-up and eventual reporting to the public health department.

All specimens for culture and sensitivities will follow these guidelines for send out to Sierra Vista Regional Health Center Reference Laboratory. All collection policies and procedures for SVRHC microbiology will be adhered to.

All microbiology reports will be sent to Infection Control. The lab manager will be responsible for monitoring organisms on a monthly basis and will be responsible for receipt of all reports in the absence of infection control.

Reviewed: 09/2008, 5/09, 12/13

Revised: 9/08, 5/09, 12/13, 06/14
## 1. Patient Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's Name (Last)</td>
<td></td>
</tr>
<tr>
<td>(First)</td>
<td></td>
</tr>
<tr>
<td>(Middle initial)</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
</tr>
<tr>
<td>Race (Check all that apply):</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
</tr>
<tr>
<td>Pacific Island Native American</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian/Pacific Islander</td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian/Pacific Islander</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Patient's Occupation or Student</td>
<td></td>
</tr>
<tr>
<td>Guardian (for minors)</td>
<td></td>
</tr>
<tr>
<td>Date of Accident</td>
<td></td>
</tr>
</tbody>
</table>

## 2. Reportable Condition Information / Lab Results

<table>
<thead>
<tr>
<th>Date Collected</th>
<th>Date Received</th>
<th>Specimen Type</th>
<th>Lab Test</th>
<th>Lab Result</th>
<th>Reporting Service</th>
<th>Provider Name &amp; Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## 3. Reporter and Provider Information

<table>
<thead>
<tr>
<th>Date Collected</th>
<th>Date Received</th>
<th>Specimen Type</th>
<th>Lab Test</th>
<th>Lab Result</th>
<th>Reporting Service</th>
<th>Provider Name &amp; Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## 4. Sexually Transmitted Diseases (STD) and HIV/AIDS

<table>
<thead>
<tr>
<th>Disease</th>
<th>Date of Last Negative Test</th>
<th>Type of Contact</th>
<th>Gender</th>
<th>Persons Only</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Secondary</td>
</tr>
<tr>
<td>Chlamydia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Congenital</td>
</tr>
</tbody>
</table>

## 5. Hepatitis Panel

<table>
<thead>
<tr>
<th>Hepatitis A Serology Results</th>
<th>Hepatitis B Serology Results</th>
<th>Hepatitis C Serology Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>PP HA</td>
<td>S Ag</td>
<td>HIV 1</td>
</tr>
<tr>
<td>S P</td>
<td>H Ag</td>
<td>HIV 2</td>
</tr>
<tr>
<td>Total</td>
<td>Anti H B</td>
<td>Anti C</td>
</tr>
<tr>
<td>Anti H A</td>
<td></td>
<td>Anti C</td>
</tr>
</tbody>
</table>

## 6. Tuberculosis (TB)

<table>
<thead>
<tr>
<th>Site of Infection</th>
<th>Tuberculosis Results</th>
<th>MDR/HRDF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Comments
Arizona Administrative Code* Requires Providers To:

REPORT 'EM
to the Local Health Department Phone#

Submit a report by telephone or through an electronic reporting system authorized by the Department within 24 hours after a case is diagnosed, treated, or detected or an occurrence is detected.

If a case or suspect case is a food handler or works in a child care establishment or a health care institution, instead of reporting within the general reporting deadline, submit a report within 24 hours after the case or suspect case is diagnosed, treated, or detected.

Submit a report within one working day after a case or suspect case is diagnosed, treated, or detected.

Submit a report within five working days after a case or suspect case is diagnosed, treated, or detected.

Submit a report within 24 hours after detecting an outbreak.
Cochise Regional Hospital
Laboratory Procedures

Laboratory Role in Surveillance and Infection Control

POLICY

It is the policy of Cochise Regional Hospital Laboratory to establish guidelines for information and data collection to be provided to the infection control program, and provide as complete as possible a picture of the microbiological risks, trends, and outcomes in the facility.

POLICY

The Laboratory will provide to the Infection Control Nurse a copy of all serology, virology, and microbiology reports, including multi-drug resistant strains, on a daily basis to assist in the surveillance program. This report will include activity from all departments in the facility.

The Microbiology Department at Sierra Vista Regional Health Center will provide antibiotic profiles and antibiotic sensitivity patterns of the isolated bacteria. This information can be used to identify trends, outbreaks, and the emergence of resistant organisms in the facility, and provide useful data on the utilization of antibiotics.

The Laboratory will be responsible for reporting positive results on those diseases requiring reporting to the Public Health Department through the Medsis system as well as infection control nurse, except those which require immediate reporting by the facility. (see Attachment A under 2.B.49).

Laboratory will notify Infection Control, Nursing Supervisor and attending physician of any positive acid-fast smears or cultures on inpatients or outpatients.

Laboratory will participate in the Infection Control Committee.

Effective: 7/99

Reviewed: 0/00, 09/08, 5/09, 6/09, 12/13

Revised: 9/08, 5/09, 12/13, 06/14
Cochise Regional Hospital
Risk Management Policies

Sentinel Event Policy

POLICY - It is the policy of Cochise Regional Hospital and the Laboratory to adhere to the following concerning sentinel events.

DEFINITION

Sentinel event - An avoidable, undesirable, and unexpected occurrence that involves the loss of patient life, limb, or functioning and/or that has the potential to adversely affect the good name or reputation of the organization.

POLICY - It is the policy of Cochise Regional Hospital and the Laboratory to adhere to the following concerning sentinel events.

Sentinel events may be identified internally by organization, staff, or through reports from patients or external agencies.

Any event that by law requires reporting to an external organization is considered sentinel and must be handled as outlined in this policy.

Interdisciplinary assessment is initiated by the Quality and Safety Committee or Administrator.

Interdisciplinary assessment uses root-cause analysis procedures to identify systems issues and events that negatively affect the process of care in a case or could potentially impact the care for other patients. The goal is to prevent any reoccurrence of the sentinel event.

The Medical Executive Committee is responsible for evaluating sentinel events and develop action plans to address identified issues. Action plans must involve monitoring to measure the plan’s effectiveness.

Plans of action developed are forwarded to the Quality and Safety Committee for critical evaluation. If deemed appropriate by the Quality and Safety Committee, the action plan and monitoring plan will be implemented by individuals and departments identified in the action plan.

If the Quality and Safety Committee determines the interdisciplinary assessment is incomplete and the analysis or action plan in unacceptable, the matter is referred back to the team for further work.
If the issue is considered beyond the scope of the Interdisciplinary Assessment Team or Task force to resolve, the matter is referred for direct action by the Administrator.

The time frame for analysis and action will depend on the nature, complexity, and severity of the sentinel event. However, in no case should an initial analysis of a case exceed 15 days from the date the event was identified and first reported. Teams assigned to evaluate and propose action for sentinel events will report on their progress to the Quality and Safety Committee every 30 days until evidence indicates the cause of the event has been effectively addressed.

The Quality and Safety Committee will track resolutions through the review of trend data. If the desired outcomes are not obtained by action plan or within a specific time frame, the matter will be referred for intervention to the Administrator.

Physician-specific performance issues identified in interdisciplinary assessment will be referred to the Medical Staff Executive Committee for action.

PROCEDURE

Once identified, a sentinel event is immediately reported to the Quality Management/Risk Management department. The Quality Management/Risk Management Department makes sure any other required internal reporting is accomplished as soon as possible.

The Quality Management or Risk Management Department immediately notifies the Administrator and chairperson of the Quality and Safety Committee of the sentinel event.

The Quality Management/Risk Management Department conducts an initial investigation and reports results to the Quality and Safety Committee Council. If deemed necessary by the Administrator, a special session is held to address the sentinel event.

The Quality Management/Risk Management Department will make sure that any required reporting to external agencies is completed within the specific time period and will brief the Administrator prior to any external reporting.

The Quality and Safety Committee appoints an Interdisciplinary Assessment Team and chairperson, or refers the event to an existing quality team.
As soon as possible, and in collaboration with the Quality Management/Risk Management Department, the Interdisciplinary Assessment Team chairman organizes meetings of the team, facilitates team’s meetings and deliberations, and documents the process.

The Interdisciplinary Assessment Team meets and reviews the case, conducts interviews, completes a Root Cause Analysis, prepares records of findings and action plans, assigns responsibilities for action steps, sets deadlines for completion, ensures the reporting of action plan results, and reports findings and actions taken as the result of the sentinel event to the Quality and Safety Committee.

The Interdisciplinary Assessment Team meets and reviews the case, conducts interviews, completes a Root Cause Analysis, prepares records of findings and action plans assigns responsibilities for action steps, sets deadlines for completion, ensures the reporting of action plan results, and reports finding and actions taken as the result of the sentinel event review to the Improving Organizational Performance Council.

The Interdisciplinary Assessment Team will report within a time frame established by the Improving Organization Performance Council.

The Improving Organizational Performance Council may specify that interim reports of analysis and action be made to the Administrator or other designated individual(s).

The Improving Organizational Performance Council team critically evaluates interdisciplinary assessment action plans and reports, accepts appropriately conducted team actions and monitoring plans, refers incomplete or unacceptable action plans to the Interdisciplinary Assessment Team to resolve, and forwards acceptable action plans to the Administrator.

The Improving Organizational Performance Council reviews trends and data from monitoring plans to see that desired improvements are achieved and reports unresolved issues to the Medical Staff Executive Committee and the Administrator.

The Governing Body is notified of any sentinel events and actions taken to address and resolve them. The Governing Body provides input, recommendations, and approval as appropriate.
Cochise Regional Hospital

Laboratory Policies and Procedures

Releasing Patient Results

Policy

It is the policy of the Laboratory at Cochise Regional Hospital to release results to the patients when an Authorization to Release Patient information form has been completed. This form is valid for one year or for the length of time indicated by the patient. A copy of this form will be kept in the Laboratory files as well as in Medical Records.

Procedure:

The following steps will be taken when a request for patient results has been received:

1. Ask patient if an Authorization to Release Patient Information has been completed.

2. Check file for completed form.

3. If no form is on file, have patient complete form with proof of positive identification using a photo I.D.

4. Notify patient that the results will be sent via mail within 1 (week) and the ordering physician will also be notified with 1 (one) working day of the request.

5. Provide ordering physician with courtesy call that patient has requested testing information and that the information will be sent out within 1 (one) week.

6. Document that physician was called on the authorization form as well as the date the results were sent. Make one copy for Laboratory files and send the original to Medical Records.

7. File authorization form in top drawer of Laboratory file cabinet.
Authorization to Release Patient Information

I HEREBY AUTHORIZE:
☐ SOUTHEAST ARIZONA MEDICAL CENTER
☐ (Name and Address of Disclosing Agency)

TO DISCLOSE THE INFORMATION SPECIFIED BELOW FROM THE HEALTH RECORDS OF:
Name:

THIS INFORMATION IS TO BE DISCLOSED TO:
(Name and Address of Receiving Agency/Healthcare Provider)

COVERING THE FOLLOWING: (Please check one)
☐ Date(s) of Service
☐ All visit dates

FOR THE PURPOSE OF:
☐ Continued Treatment
☐ Billing
☐ Personal
☐ Investigation and/or Litigation
☐ Insurance
☐ Other:

INFORMATION IS TO BE RELEASED:
☐ Entire Medical Record
☐ Discharge Summary
☐ Operative Report
☐ History & Physical Examination
☐ Consultation Report
☐ Emergency Department Record
☐ Laboratory
☐ X-ray (Imaging) Report
☐ Other:

I consent to the release of the following information:
☐ Acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection
☐ Behavioral health service/psychiatric care
☐ Treatment for alcohol and/or drug abuse

POSSIBILITY OF REDISCLOSURE: I understand that any information released may be subject to re-disclosure and no longer protected by state and federal regulations.

EXPIRATION AND REVOCATION: I understand that this authorization is valid for 1 year from the date I sign it or ___ days (if less), or the duration of _______ (event). I have the right to revoke this authorization in writing at any time. The revocation will take effect on the day it is received except to the extent it has already been acted upon or if the authorization was obtained as a condition of obtaining insurance coverage.

IF THE PATIENT IS UNABLE TO SIGN, PLEASE STATE REASON:

Signature of Patient / Guardian / Legal Representative

Date signed

Relationship to patient

Witness / Date
Cochise Regional Hospital
Laboratory Policies and Procedures

WAIVED TESTING AND PERSONNEL

Policy: It is the policy of Cochise Regional Hospital to meet CLIA requirements for waived testing.

Purpose

On February 28, 1992, regulations were published to implement CLIA. In the regulations, waived tests were defined as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Tests

Sure Vue Strep A
Binax RSV
Quick Vue H. pylori
Quick Vue HCG (urine only)
Sure Vue Signature Mono Test Kit (whole blood only)
Binax Influenza A and B
Hemosure (Fecal occult blood)
Gastroccult (gastric occult blood)
Gastric pH (gastric occult blood)
Abbott Precision Glucometer for blood glucose testing
Bayer/Siemens Clinitek Status Analyzer
Bayer/Siemens Acetest Tablets
Bayer/Siemens Icotest Tablets
Bayer/Siemens Clinitest Tablets
Bayer/Siemens Multistix 10 SG Test Strips
Testing Personnel

1. Medical Technologist/Technicians
2. Laboratory Assistants
3. Phlebotomist-glucometer testing
4. Nursing personnel-glucometer testing

Laboratory Supervisory Personnel

1. Head of Laboratory Services/Laboratory Manager: Veronica Santiago.
2. Medical Technologist Team Leaders: Celia Rascon
Cochise Regional Hospital
Laboratory Policies and Procedures

Patient Identification for Multiple Sampling on a Single Test Order

Policy

It is the policy of Cochise Regional Hospital to identify a patient each time a sample is to be drawn on a single test order.

Procedure

Before procedure is started a final verification process must take place. This is to ensure that the patient is correct, the correct procedure is to be performed and the correct and proper site is to be used.

Below are the steps to be taken when a patient requires more than one draw on a single test order (ie. Glucose tolerances, therapeutic phlebotomy).

1. Identify patient each time specimens are to be drawn by asking patient to state name and date of birth.

2. Establish which site is to be used with the patient.

3. Verify with the patient that they understand what procedure is being performed.


5. Gather any equipment or special requirements.

6. Document process on requisition to include date and times of specimens drawn and patient verification.

7. Document any discrepancies and how they were reconciled using an incident report form.

8. Reestablish patient identity if phlebotomist or technologist leaves the area for any reason.

9. Mark the site to be used unless phlebotomist or technologist is present during entire procedure.


11. Apply adequate amount of pressure following procedure. Following therapeutic phlebotomy pressure should be applied for at least 5 minutes.

13.  Label specimen if applicable with appropriate patient information to include dates and times drawn, date of birth, name, collectors initials and identification number. Include which the hour of draw for glucose tolerance testing. (ie. Fasting, 1 hour, 2 hour, 3 hour, etc.).

Reference:

1. 2008 Laboratory Accreditation Standards - National Patient Safety Goals, Goal 1B.
Cochise Regional Hospital

Laboratory Code of Safe Practice

Policy

It is the policy of Cochise Regional Hospital Laboratory to follow all safety guidelines as put forth by hospital wide policies and procedures and all accrediting and regulatory agencies.

Guidelines

1. No food and/or drinks will be stored or consumed in the work areas of the laboratory.
2. Employees will observe universal precautions while performing work.
3. Employees will wear personal protective clothing as appropriate.
4. Employees will transport blood and body fluid specimens in approved biohazard bags and/or containers to prevent spills.
5. Fire extinguishers and blankets are available and all employees are trained annually on their use.
6. Eyewash station will be in an easy and close location to work areas as a first aid treatment.
7. Broken glass shall be picked up with a dust broom and pan for disposal in a sharps container.
8. All liquids will be handled with pipetting devices.
9. Mouth pipetting is prohibited.
10. Needles will not be recapped and shall be disposed of in a sharps container.
11. Safety equipment is available and shall be used appropriately.
12. All instruments and machines are electrically grounded and maintained on a preventive maintenance inspection schedule.
13. Employees report defective equipment immediately to Laboratory Manager and/or UHS Biomedical Group.
14. Employees are trained annually in safety practices.
15. Employees are trained annually on work related equipment operation.

16. Only authorized personnel will use diagnostic equipment.
Cochise Regional Hospital

Sierra Vista Pathology Tissue Sendouts

Policy

It is the policy of Cochise Regional Hospital to utilize Sierra Vista Pathology for pathology services and that all processes are consistent with CLIA, CMS and Joint Commission regulations and standards.

Procedure

Tissue specimens are collected by nursing and physician staff primarily in the Operating Room and Emergency Room. Some samples are collected in the Clinics.

All tissue samples are sent directly to the Laboratory for sendout. Upon arrival at the Laboratory the following steps will be taken:

1. Samples must accompanied by a histology requisition for Sierra Vista Pathology and a patient face Sheet.

2. Patient’s name, date and time of arrival to the lab, collection location, person handling specimen, specimen type, courier’s initials shall be logged onto Sierra Vista Pathology Chain of Custody Logsheet located in the processing area of the Laboratory.

3. Histology requisition should be completed by area where specimen was collected to include insurance information. Histology requisitions should be located on each nursing station as well as the Laboratory.

4. Specimens will be logged into the Pathology Laboratory Logbook.

5. The original logsheet for Sierra Vista Pathology MUST accompany the specimens.

6. Courier MUST sign Sierra Vista Pathology Logsheet.

7. A copy of the Sierra Vista Pathology Logsheet will be kept in the OR and the Laboratory Sendout Log.

Resulting

When results come back from Sierra Vista Pathology Laboratory personnel will do the following:
1. Results must be matched to the logsheet for Sierra Vista Pathology and the date of receipt and initials of processor will be documented next to the patient information.

2. A copy of results will be made for medical records and the patient’s physician.

3. A copy of all pathology reports will be maintained by the Laboratory. All records are to be kept for a period of 10 years

4. A copy of the Sierra Vista Pathology Logsheet will be sent to the Director of Nursing at the end of every month.

References

1. 2008 Laboratory Accreditation Standards, The Joint Commission -- Standards QC 5.300 and QC 5,310.
Cochise Regional Hospital
Laboratory Policies and Procedures

Surveillance of Patient Results and Related Records

Policy

It is the policy of Cochise Regional Hospital to comply with standards from CLIA pertaining to surveillance of patient results and other related records.

Procedure

1. Under the guidance and supervision of the Laboratory Manager medical technologist team leaders shall review patient results for errors, critical values and outlier abnormal results on a daily basis, unacceptable quality control, results not correlating to patient criteria and when results on any one patient is inconsistent.

2. The Laboratory Manager will review work records, equipment records, critical values called and quality control records on a monthly basis.

3. All records reviewed will be dated and initialed by individual(s) performing review.

4. Any handwritten or manually entered data will be reviewed by medical technologist team leaders for accuracy and/or errors.

5. Patient results may be released as long as all quality control is within specified ranges, patient results are below linearity ranges and results are consistent with patients condition, age, sex, diagnosis, clinical data and relationship to other testing parameters.

6. Electronic and printed test results will be reviewed for errors on a quarterly basis. Results will be documented and submitted in writing to the Laboratory Manager. This will validate the accuracy of the transmission of data from the instrument to the target location (LIS).

References:

1. 2008 Laboratory Accreditation Standards, The Joint Commission - Standard QC 1.90
Reviewed and Approved by:

Veronica Santiago  
Laboratory Manager  

Approval Date: 7/1/14

Approved by the Board

Seth Guterman MD  
Chairman of the Board  

Approval Date: 7/15/14