### GENERAL POLICIES

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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 6AM to 2100. 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

Hours of operation for outpatient services are as follows:
Remote Draw Station — 7AM-1530 M-F; 8AM-1200 Sat
Cochise Regional Hospital
Laboratory Policies

TESTS PERFORMED

<table>
<thead>
<tr>
<th>CHEMISTRY</th>
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<tbody>
<tr>
<td>Acetaminophen (Tylenol)</td>
<td>Liver Profile</td>
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<tr>
<td>Acetone</td>
<td>Magnesium</td>
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<tr>
<td>Albumin</td>
<td>Microalbumin</td>
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<tr>
<td>Alkaline Phosphatase</td>
<td>Micro-Total Protein</td>
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<tr>
<td>ALT (SGOT)</td>
<td>Phosphorus (PO4)</td>
</tr>
<tr>
<td>Ammonia</td>
<td>Potassium (K)</td>
</tr>
<tr>
<td>Amylase</td>
<td>PSA</td>
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<tr>
<td>AST (SGOT)</td>
<td>RA Factor</td>
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<tr>
<td>Basic Metabolic Profile</td>
<td>Rubella IgG</td>
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<tr>
<td>Beta HCG, quantitative</td>
<td>Salicylate (Aspirin)</td>
</tr>
<tr>
<td>Bilirubin, Total, Direct, Neonatal</td>
<td>Serum Pregnancy (qualitative)</td>
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<tr>
<td>BNP</td>
<td>Sodium (NA)</td>
</tr>
<tr>
<td>BUN</td>
<td>Troponin</td>
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<tr>
<td>Calcium</td>
<td>Theophylline</td>
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<tr>
<td>Carbamezapine (Tegretol)</td>
<td>Triglycerides</td>
</tr>
<tr>
<td>Carbon Dioxide (CO2)</td>
<td>TIBC</td>
</tr>
<tr>
<td>Chloride (Cl)</td>
<td>Total Protein</td>
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<tr>
<td>Cholesterol</td>
<td>TSH</td>
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<tr>
<td>CK MB (mass)</td>
<td>Uric Acid</td>
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<tr>
<td>Comprehensive Metabolic Profile</td>
<td>Urine Creatine</td>
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<td>----------------------------------</td>
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<tr>
<td>CPK</td>
<td>Urine Protein</td>
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<tr>
<td>Creatine</td>
<td>Urine Pregnancy (qualitative)</td>
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<td>Creatine Clearance</td>
<td>Valproic Acid</td>
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<td>CSF Glucose</td>
<td>CSF Protein</td>
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<tr>
<td>Dilantin (Phenytoin)</td>
<td>Digoxin</td>
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<tr>
<td>Drug of Abuse (DOA)</td>
<td>Ethanol (ETOH)</td>
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<td>FT4</td>
<td>Glucose Random/Fasting</td>
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<td>Gentamicin</td>
<td>Glucose Tolerance Test</td>
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<tr>
<td>LDH</td>
<td>Lipid Profile</td>
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### BLOOD BANK

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<th>ABO/Rh</th>
<th>Antibody Screen</th>
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<tbody>
<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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<td>Platelet Pheresis</td>
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### TESTS PERFORMED

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<th>MICROBIOLOGY</th>
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<tr>
<td>Complete Blood Count (CBC)</td>
<td>C. Difficile Toxin A</td>
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<tr>
<td>CSF/Body Fluid Cell Count/differential</td>
<td>Fecal/Gastric Occult Blood</td>
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<tr>
<td>Hemoglobin</td>
<td>Gram Stain</td>
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<tr>
<td>Hematocrit</td>
<td>H. pylori</td>
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<tr>
<td>Manual Differential</td>
<td>Influenza A and B</td>
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<tr>
<td>--------------------------</td>
<td>-----------------------------------</td>
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<tr>
<td>Platelet Count</td>
<td>KOH prep</td>
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<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>
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<tr>
<td>Protome (PT)</td>
<td>Urine Complete/Microscopic</td>
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<td>Partial Thromboplastin (PTT)</td>
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<table>
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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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<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
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<td>1</td>
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<tr>
<td>Med Tech (12hr nights)</td>
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<td>Phlebotomist (8hrs Draw St)</td>
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<tr>
<td>PRN Phlebotomist (Draw St)</td>
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<td>1</td>
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<tr>
<td>PRN Phlebotomist (Weekend days)</td>
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Effective Date: 3/98
Reviewed: 11/08, 5/09, 12/13
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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.

Effective: 3/98

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

Revised: 5/09, 12/13, 06/2014
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,

Effective Date: 3/98
Reviewed: 11/08, 5/09, 12/13
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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 from? 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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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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Revised: 5/09, 12/13, 06/14
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.

Effective Date: 3/98
Reviewed: 11/08, 5/09, 12/13
Revised: 5/09, 12/13, 06/14
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).

Effective Date: 3/98
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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.

Effective Date: 3/98

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

Revised: 5/09, 12/13, 06/14
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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Revised: 5/09, 12/13, 06/14
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<th><strong>BLOOD BANK</strong></th>
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<tr>
<td>Direct Coombs (DAT)</td>
<td>Partial Thromboplastin (PTT)</td>
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<tr>
<td>Crossmatch</td>
<td>Prothrombin Time (PT)</td>
</tr>
<tr>
<td>Transfusion Reaction WorkUp</td>
<td>D.Dimer</td>
</tr>
<tr>
<td>Acetone</td>
<td></td>
</tr>
<tr>
<td><strong>HEMATOLOGY</strong></td>
<td></td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>CBC/Hemogram (Automated Blood Count)</td>
</tr>
<tr>
<td>Alcohol (medical only)</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Amylase</td>
<td>Hernatocrit</td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td>Platelet Count</td>
</tr>
<tr>
<td>BNP</td>
<td>Sed Rate</td>
</tr>
<tr>
<td>BUN</td>
<td>Spinal Fluid Cell Count</td>
</tr>
<tr>
<td>Bilirubin</td>
<td></td>
</tr>
<tr>
<td>CKMB (mass)</td>
<td></td>
</tr>
<tr>
<td>CPK</td>
<td>Complete Urinalysis with Reflex micro</td>
</tr>
<tr>
<td>Creatinine</td>
<td></td>
</tr>
<tr>
<td>CSF Protein</td>
<td></td>
</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>
</tr>
<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>
</tr>
<tr>
<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>Troponin</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>
</tr>
</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)/m1

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>
</tr>
</thead>
<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>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</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>
</tr>
<tr>
<td>Phosphorus</td>
<td>1.0 mg/dl</td>
<td>9.0 mg/dl</td>
</tr>
<tr>
<td>Potassium</td>
<td>2.8 mmol/L</td>
<td>6.2 mmol/L</td>
</tr>
<tr>
<td>Salicylate</td>
<td>N/A</td>
<td>50.0 m=g/dl</td>
</tr>
<tr>
<td>Sodium</td>
<td>120 mg/dl</td>
<td>160.0 mg/dl</td>
</tr>
<tr>
<td>Tegretol/Carbamazapine</td>
<td>N/A</td>
<td>15.0 ug/dl</td>
</tr>
<tr>
<td>Theophylline</td>
<td>N/A</td>
<td>21.0 ug/dl</td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>N/A</td>
<td>200.0 ug/ml</td>
</tr>
<tr>
<td>Troponin</td>
<td>N/A</td>
<td>&gt;0.5 ng/ml</td>
</tr>
</tbody>
</table>

**Hematology:**

<table>
<thead>
<tr>
<th></th>
<th>less than</th>
<th>greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematocrit</td>
<td>20%</td>
<td>60%</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>7.5 g/dL</td>
<td>20.0 g/dL</td>
</tr>
<tr>
<td>Platelets</td>
<td>40.0 x 10(3)/ml</td>
<td>999.0 x 10(3)/ml</td>
</tr>
<tr>
<td>Protime</td>
<td>N/A</td>
<td>60.5 sec</td>
</tr>
<tr>
<td>Protime (INR)</td>
<td>N/A</td>
<td>3.5</td>
</tr>
<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>
</tr>
<tr>
<td>-----------</td>
<td>---------------</td>
<td>----------------</td>
</tr>
</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
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 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 recipient 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 patient’s 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
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

DOWN TIME 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>
</tr>
</thead>
<tbody>
<tr>
<td>Initials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cochise Regional Hospital

Laboratory Policies

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

1   2   3   4   5   6   7   8   9   10  11  12  13
14  15  16  17  18  19  20  21  22  23  24  25
26  27  28  29  30  31

Daily Cleaning

Counters

Screens

Keyboards

Phones

Centrifuges

Above Cabinets

Refrigerators

Breakroom

Instruments

Sinks

Pending Log

Fax Log

SV Reports

OP Charts

PRBC/Blood Units

Weekly Duties

Stain Jars

Water/Bleach Bottles

Inventory
Eye Wash Station Monthly Duty Water Bath
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.

Immunoochemistry — 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 IL’s Quality Assurance Program.
3. 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

<table>
<thead>
<tr>
<th>Three Controls in Use</th>
<th>Accept the run unless:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. One control is greater than 3 S.D. from the mean.</td>
<td></td>
</tr>
<tr>
<td>2. Two of the controls are greater than 2 S.D, but less than 3 S.D from the mean.</td>
<td></td>
</tr>
<tr>
<td>3. One control is greater than 2 but less than 3 S.D from the mean on two successive runs.</td>
<td></td>
</tr>
<tr>
<td>4. Patient results appear unlikely, regardless of control results.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Two Controls in Use</th>
<th>Accept the run unless:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. One control is greater than 3 S.D. from the mean.</td>
<td></td>
</tr>
<tr>
<td>2. Both controls are greater than 2 S.D, but less than 3 S.D from the mean.</td>
<td></td>
</tr>
<tr>
<td>3. One control is greater than 2 but less than 3 S.D from the mean on two successive runs.</td>
<td></td>
</tr>
<tr>
<td>4. Patient results appear unlikely, regardless of control results.</td>
<td></td>
</tr>
</tbody>
</table>

| 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.

Effective: 5/09
Reviewed: 12/13
Revised: 12/13, 06/14
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
### 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 Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Requisitions</td>
<td>2 years</td>
</tr>
<tr>
<td>Log Books</td>
<td>2 years</td>
</tr>
<tr>
<td>Quality Control Records</td>
<td>2 years</td>
</tr>
<tr>
<td>Equipment Records</td>
<td>2 years for performance (for life of equipment for major repairs and annual maintenance)</td>
</tr>
<tr>
<td>Proficiency Testing</td>
<td>2 years</td>
</tr>
<tr>
<td>Instrument Printouts</td>
<td>2 years</td>
</tr>
<tr>
<td>Discontinued Procedures/Policies</td>
<td>2 years</td>
</tr>
<tr>
<td>Blood Samples</td>
<td>7 days</td>
</tr>
<tr>
<td>Urine Samples</td>
<td>24 hours</td>
</tr>
<tr>
<td>Blood Smears</td>
<td>2 months</td>
</tr>
</tbody>
</table>

#### Blood Bank

<table>
<thead>
<tr>
<th>Record Type</th>
<th>Retention Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing Records</td>
<td>5 years</td>
</tr>
<tr>
<td>Reports</td>
<td>5 years</td>
</tr>
<tr>
<td>Quality Control</td>
<td>5 years</td>
</tr>
<tr>
<td>Donor/Recipient Records</td>
<td>Indefinitely</td>
</tr>
</tbody>
</table>

#### Histology/Cytology
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 4 degreesC 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 4degrees and 30degrees 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. Sop 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 he 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 he 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
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Laboratory Manager
Approval Date: 7/1/14

Approved by the Board

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Chairman of the Board
Approval Date: 7/15/14