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Abbott ARCHITECT Chemistry System Analyzer Operation

Document type: Procedure

I. PURPOSE AND OBJECTIVE:

To describe how to operate the Abbott ARCHITECT Chemistry System Analyzer

II. INTRODUCTION:

The Abbott ARCHITECT c4000, c8000 and c16000 Chemistry Analyzers are fully-automated clinical chemistry systems allowing random, continuous access and priority processing. The analyzer is designed for the in-vitro determination of a variety of chemistries by photometric or potentiometric measurement.

III. CLINICAL SIGNIFICANCE:

Refer to **Attachment A** for Clinical Significance.

IV. SPECIMEN COLLECTION AND HANDLING:

The Abbott ARCHITECT c System can be used to analyze, serum, plasma, urine, cerebral spinal fluid (CSF), and other body fluids. Consult the online, Beaumont Laboratory Test Directory or the assay specific package insert for appropriate specimen types. Samples can be tested in the primary collection tube, Abbott Sample Cups, and false bottom aliquot tubes.

A. **Collection Requirements:**

1. Follow all universal precautions for collecting blood by venipuncture to avoid specimen hemolysis.
2. Verify the correct specimen type is used. The ARCHITECT system does not verify

specimen type.

3. It is common for PEAK Therapeutic Drug measurements to be drawn 1 hour following the cessation of an IV infusion as indicated in the Lab Test Directory. Dosage date and time are included in the report when indicated at collection. Results are evaluated in the Laboratory Information System using the reference range for a PEAK measurement.
4. It is common for TROUGH Therapeutic Drug measurements to be drawn just prior to the next dosage administration as indicated in the Lab Test Directory. Dosage date and time are included in the report when indicated at collection. Results are evaluated in the Laboratory Information System using the reference range for a TROUGH measurement.

B. **Specimen Preparation and Storage**

1. Ensure that specimens collected in tubes containing a gel separator have 8mm of serum above the gel to avoid contamination of the specimen during pipetting.
2. Visually inspect all samples for bubbles prior to loading. Remove with a clean applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
3. Verify serum and plasma specimens are free from fibrin, red blood cells, or other particulate matter.
4. Ensure complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting times. If centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
5. Remove tops from specimen tubes prior to loading on the sample handler.
6. Samples tested by automated track analysis are loaded at the IOM (Input Output Module). Samples may be loaded with or without the cap as determined by the lane that the sample is loaded. Samples may be loaded before or after centrifugation as determined by the lane that the sample is loaded. The lanes are marked for guidance. Inspect the sample when loading to ensure that the tube is sufficiently filled. Microtainer samples and short draws will be aliquoted to a false bottom tube before loading on the IOM. Analyzers that are connected to a track may be loaded directly using the sample carousel.
7. Refer to **Attachment H** for Specimen Stability
8. **Sample Volume:** Required sample volume can be obtained from the Order List Report after order is placed. The stated volume includes the 50 µL dead space using an Abbott sample cup.

V. REAGENTS:

References Reagents, typically consisting of an R1 and R2 cartridge, are obtained from Abbott Diagnostics, Abbott Park, IL, USA. Some reagents are ready to use and some require preparation. Refer to **Attachment B** (Architect Chemistry Reagent Reference Guide) for a detailed list of preparation and

storage requirements.

VI. EQUIPMENT:

The ARCHITECT consists of three primary components. The complete Operations Manual can be accessed from the instrument screen. The Operator selects Overview ICON and then Operations Manual.

A. **SCC (System Control Center)** provides a common interface across all ARCHITECT System Configurations. From the SCC you can:
    1. Configure the system
    2. Enter patient, control, and calibration orders
    3. Review patient results, control data, and calibration results
    4. Control the processing module(s) and the sample handler
    5. Perform system diagnostics and maintenance procedures
    6. Receive test orders and diagnostic data from a host computer
    7. Transfer test results to a host computer

B. **PM (Processing Module)** performs all sample processing activities from aspiration to final read.

C. **RSH (Robotic Sample Handler)** transports samples through the ARCHITECT system.

VII. SUPPLIES:

A. **Reagent cartridges**
Reagent cartridges are containers used in the reagent supply centers to hold the reagents used during operation. They may also hold Wash Solution, Saline and Water Bath Additive.

B. **Calibrators**
Calibrators are samples that contain known concentrations of analyte. A variety of calibrators (single and multiconstituent) are used on the system. See **Attachment C** for required calibrators.

C. **ICT module**
The ICT module is an integrated chip located within the ICT unit that contains the Na+, K+, Cl-, and reference electrodes. The warranty for the ICT module is 20,000 samples or three months post-installation, whichever comes first. ICT module expires 9 months after manufacture.

D. **ICT cleaning fluid**
ICT Cleaning Fluid is a cleaning agent prepared by the operator and used during daily maintenance procedures to clean the ICT module. The ICT Cleaning Fluid is supplied as a two-part product, consisting of a liquid and a powder.

E. **Bulk solutions**
Bulk solutions are liquid solutions provided in large quantities that are used in sample processing. Three bulk solutions are loaded onto weighted platforms behind the supply center door of the processing module. These include ICT reference solution, Alkaline Wash, and Acid Wash.

1. **ICT reference solution**
   ICT Reference Solution (2000 mL bottle) is a mid-concentration standard. It is aspirated and analyzed by the ICT module before and after each sample to provide a reference potential used to calculate results.
2. **Alkaline wash**
   Alkaline Wash (500 mL bottle) is an alkaline wash solution used by the cuvette washer to clean the cuvettes after sample analysis.
3. **Acid wash**
   Acid Wash (500 mL bottle) is an acidic wash solution used by the cuvette washer to clean the cuvettes after sample analysis. A dilution of the acid wash solution may also be used for probe washing.

F. **Sample Cups**

1. Aliquot tubes- Sarstedt SC TUBE 6.5 mL 13x90 (60.503.010)
2. False bottom Aliquot tubes- Sarstedt FB Tube 2.5 mL (60.614.065)

VIII. MAINTENANCE:

A. Maintenance is performed Daily, Weekly, Monthly, Quarterly, and As Needed. Refer to the onboard system maintenance procedures for details and instructions. The Maintenance Procedures are accessed by selecting System from the menu bar and selecting Maintenance. The scheduled Maintenance procedures are displayed on the "To do" tab. The Daily, Weekly, Monthly, Quarterly, and As Needed tabs are selected to display procedures in the selected category. Select the desired procedure and then select **F5- Perform**. A confirmation message displays. Select **OK** to perform. The Maintenance Perform window displays with a description of the procedure and instructions. You may close the window to access other screens and windows.

IX. CALIBRATION:

A. Manufacturer calibrators or water blank are used to calibrate each assay at specified intervals. Refer to **Attachment C** for a detailed list of calibrators.

1. Calibration must be performed when:
   a. A new reagent lot number is used.
   b. Documentation accompanying a new version of an existing assay file states calibration is required.
   c. A new assay file that requires calibration is installed.
   d. The calibration curve has expired.
   e. A calibration or recalibration has a status of Failed.
2. Calibration may be necessary when:
   a. Assay control values are out of specification.
   b. Certain system maintenance/component replacement procedures are performed.

c. Certain specific error codes are obtained.
Note: A Calibration with a status of Pending quality control (QC) is considered an active curve but, cannot be used to process tests until at least one level of control is completed successfully. A calibration may be manually failed by selecting the Fail Curve button on the Calibration curve window.

B. **Automated Assay Calibration**
Automated assay calibration is the process the system uses to automatically order calibrations by associating a SID (sample ID) with a predefined calibrator. For automated assay calibration a barcode label is used for each calibrator level. Assays using water as a blank do not require a barcoded calibrator. The water is dispensed by the sample probe. When a barcode is configured and scanned the system automatically processes the tests configured for that SID. The orders may be viewed on the order status screen. The Order List may be printed to obtain calibrator volumes necessary for calibration.

C. **Multiple reagent lots**

1. When multiple reagent lots for an assay are loaded on the system and the sampling process for a calibration order is ready to begin, the system determines the lots to calibrate by using the following rules:
    a. If all reagent lots do not have a current calibration status of Active or Pending QC, the system calibrates all lots on the system
    b. If all reagent lots for the assay currently have a calibration status of Active or Pending QC, all reagent lots loaded on the system will be recalibrated.
    c. If some reagent lots have a status of Active or Pending QC and some do not, the system calibrates only the reagent lot without an active calibration.
2. For the **c16000** the calibration status is specific to one line. If a reagent with an active calibration status is moved from one line (A or B line) to the other and is then scanned, the calibration status for the new location is NO CAL. To avoid recalibration:
    a. Do not move reagents from one line to the other.
    b. Do not load on a different line when replacing reagents.

D. **Curve storage**
The ARCHITECT system stores active, inactive and failed calibration curves.

1. Active calibrations:
    a. Stores the processing module-specific calibration as the active curve for that reagent lot.
    b. Replaces the previous calibration curve, which becomes inactive.
    c. Automatically defaults to the active curve for the onboard reagent lot.
    d. Stores one active curve for up to FOUR different reagent lot numbers of each assay.
    e. Replaces the oldest active curve if a fifth reagent lot calibrates

successfully.

2. Inactive calibrations:
    a. Stored for 3 months.
    b. All calibration curves are removed from the system when the last kit of a reagent master lot is deleted.
    c. Deletion occurs when the reagent kit storage capacity is exceeded.

X. QUALITY CONTROL:

A. The following are minimum requirements and should take into account the Quality Control (QC) stability by test:
    1. For electrolytes (Na, K, Cl) by ion selective electrodes (ISE)
        a. Run serum QC materials 2 levels every 8 hours; laboratories may elect to include CO2 in this electrolyte QC protocol.
        b. Run urine QC materials 2 levels twice daily for electrolytes
    2. For all other high volume tests (routine or stat)
        a. Run at least 2 levels of QC material twice daily.
    3. For low volume tests, depending on individual lab workflow
        a. Run at least 2 levels of QC material when samples(s) are received OR
        b. Run at least 2 levels of QC material every 24 hours
    4. After a calibration, all control levels must be run
    5. Results should not be reported when QC rules are violated unless approved by supervisory staff.

XI. SPECIAL SAFETY PRECAUTIONS:

Universal precautions are indicated when handling patient specimens and quality control materials. Spills and accidents should be addressed immediately. Refer to the appropriate safety data sheet (SDS) for specific reagent information.

XII. PROCEDURE:

A. **Start-up/Shutdown Analyzer**
    1. **Power off the Analyzer**
        a. Select F3- Shutdown on the Snapshot screen. A confirmation message displays.
        b. Select OK to initiate shutdown.
        c. Wait for the information window to display, and then simultaneously press the CTRL+ALT+DELETE keys. The Confirm Exit window displays.

d. Perform one of the following:

   i. If the dialog window displays leave the "Shutdown the computer" option selected, select OK and then wait for the information window to display.

   ii. If the red power off button displays, select  .

e. Locate the central processing unit (CPU) to access the power switch.

f. Press and hold the power switch on the front to turn off the power to the SCC.

g. Turn off power to the processing module(s) by moving the power switch down. The power switch is in the rear of each testing analyzer, except for the rack sample handler (RSH). The RSH power switch is located on the left side of the integrated system.

2. **Power on the Analyzer**

   a. Press the power switch on the front of the CPU to turn on the SCC.

   b. Wait for the Log on window to display. It may take several minutes.

   c. Ensure the processing module(s) have been powered off for 1 minute and then move the power switch up to turn on power.

   d. Log on to the SCC as a general operator or system administrator.

   e. To change the status of the processing module(s) from Stopped to Ready select F-5 Startup from the Snapshot screen.

3. **Emergency Shutdown**

   a. Press the Emergency Stop Button located on the front of the analyzer. For multi-module systems use the emergency stop button for the processing module farthest to the right when facing the system to stop the sample handler and the processing module.

   b. The analyzers may also be powered down by moving down the power switch located on the rear of each analyzer.

B. **Loading Supplies**

1. Check consumable inventory before processing samples using the Supply status screen.
2. View the bulk solutions and the solutions in the reagent supply centers. The system must be in ready to load or update bulk supplies.
3. View the onboard solutions in the sample carousel.
4. From the Snapshot screen select **F-7 Pause** to change status from running to ready.
5. Adjust levels if necessary by selecting **F3-Adjust level**.
6. Update supplies when replacing by selecting **F2- Update supplies. DO NOT** combine partial bottles of bulk solution.
7. Scan Barcodes to update Lot Numbers and Expiration dates.

8. Select Done.
9. The supply status screen displays the updated level. The system automatically flushes the replaced solution before testing is performed.

C. **Loading Reagent Cartridges**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Invert the reagent cartridge gently to ensure homogeneity.
3. Remove the cartridge cap.
4. Remove air bubbles. (An applicator stick can be used for this purpose).
5. When the module is Scheduled Pause, the reagent carousel advance buttons will illuminate when the reagent supply center is available for loading.
6. Press the carousel advance button to advance the reagent supply center carousel.
7. Place the reagent cartridge in an open position using the reagent carriers if needed. Ensure that the reagent is placed on the correct Line.
8. Close the reagent supply center cover.
9. **Select F5 – Scan** on the Reagent status screen to update the reagent inventory.

D. **User Defined Reagents**

User defined reagents include sample diluents and reagents not supplied by Abbott.

1. **Configure a reagent Kit**
    a. The operator needs to be signed in as 'ADMIN" (password: ADM).
    b. Select System, Configuration, Assay Categories, Reagent settings, F-6 Configure.
    c. From the displayed Reagent Settings window, select the Lot number list button, and then select New Lot from the list.
    d. Enter the lot number.
    e. Enter a unique serial number to identify the cartridge.
    f. Select the Cartridge size.
    g. Select Add Kit.
    h. Select Done to save changes.
2. **Loading a reagent Kit**
    a. Select Reagent, Reagent Status
    b. Select **F-6 Assign Location**
    c. Select the desired reagent from the reagent kits table.
    d. Note the displayed cartridge size.
    e. Label the cartridge with the reagent name and expiration date.
    f. Pour the reagent into the specified cartridge type.
    g. Remove air bubbles, if present, with a clean applicator stick and place the

cartridge in the assigned location in the reagent supply center.

h. Select **Done** on the Assign location wheel to return to the Reagent Status screen.

i. Scan the reagent carousel to update.
NOTE: User defined reagent can be reset when using the same lot number by selecting the reagent and selecting **F-8 Reset** on the Reagent Status screen

E. **Ordering a Calibration**

1. Check the Calibration Status Screen to determine calibrations required.
2. From the **Orders** menu, select **Calibration order**.
3. Select **QC-Cal** from the menu bar and then select **Calibration.**
4. Select the carrier or carousel button.
5. In the C field enter the carrier ID manually or by scanning the barcode label attached to the carrier.
6. In the P field, enter the position. Enter 1-5 for carrier or enter 1-30 if the carousel was selected.
7. In the Assays section, select the assays to be calibrated.
8. Verify the calibrator lot number to ensure that the correct set points are used for calibration.
9. Select F-5 Assay options to specify calibration lot number if the calibrator lot number is different from the displayed lot number.
Note: The system assigns all selected assay calibrators to positions. It starts with C/P entered and assigns the calibrators in the next sequential carriers.
10. Click Done and **F-2 Add order.**
11. From the Order menu, Click Order Status
12. Click **F4- Print** to print the Order List Report
13. Load and run calibrators using Order List Report for volumes and carrier locations.

F. **Entering New Calibrator Set Points**

1. The operator needs to be signed in as 'ADMIN" (password: ADM).
2. Go to System, Configuration, QC-Cal Settings, Calibrator Set, Choose Calibrator, Configure.
3. Select the dropdown box next to the lot number.
4. Select New Lot
5. Select assays by highlighting.
6. Select Define data and enter the new values.
7. New calibrator lot can be added while the system is in running, but will not default to this lot number.

8. System must be in ready to change the default calibrator.

G. **Ordering QC**

1. From Orders menu, select Control Order
2. From the Control order screen select the appropriate option (Single Analyte or Multi-constituent).
3. Select carrier or carousel button
4. Enter Carrier ID in C field
5. Enter a position in the P field.
6. Select the Control List button and then select the desired control
7. If the desired lot number does not display in the lot box, select the Lot list button and select the desired lot.
8. Select the desired Level option.
9. Select the desired Panel and/or Assays.
10. Select **F5 Assay** options to specify assay options. Use previous/ next buttons to display each assay if more than one selected.
11. Select Done to save changes.
12. Select **F2- Add Order.**
    NOTE: Controls can be ordered manually or by loading a barcoded carrier tube. If a barcoded tube is used, all tests associated with the barcode will be tested. If the barcoded carrier tube will be used when ordering single tests or repeats, you must manually order the test and make sure that your barcode matches the QC for that order.

H. **Disable a reagent**

1. Reagents can be patient disabled from the Reagent Status Screen.
2. Highlight the reagent.
3. Select F-7 Details.
4. Select the disable for patient testing box.

I. **Testing Samples- Automation Track**

1. Place on the Sample Carousel for direct instrument loading. The Sample Carousel must be paused prior to opening the door to load samples. A solid green light on the Pause Button indicates the carousel may be loaded. Samples to be tested using the automation line are loaded at the IOM.
2. Samples to be tested using the automation line are moved to the instruments by RFID carriers on the track. Samples can be directed with a STAT Priority using the designated STAT Line at the IOM when loading. Samples tested by the automated track will be moved to an IOM for operator intervention if designated. Completed samples are taken to the storage units.

J. **Testing Samples- Integrated/Standalone Systems**

1. Place samples in the sample rack(s) for direct instrument loading.
2. Initialize the Processing Module(s) from the Snapshot screen by selecting the module(s) and **F8- Run**. Note: If the module is Stopped select **F-5 Start-up** to bring the status to ready before initiating Run.
3. Place carrier on the RSH. Ensure that the space is empty and not illuminated with a light before loading carrier. Samples with Stat Priority are loaded in Bay 1 or on the carousel.
4. Carriers with solid green lights are waiting to be tested
5. Carriers with blinking green lights have been sampled. Alternating Green and Amber blinking lights are sampled but there is a problem that will need to be addressed by the operator.
6. Check the status of the samples before unloading by going to Overview, Sample Status screen. Handle any exceptions as needed.

XIII. CALCULATIONS AND INTERPRETATIONS:

A. Patient and control results are automatically uploaded to the Instrument Manager (IM). Results needing operator attention remain in the Review Queue until released by the operator. Refer to the IM Operating Procedure.

B. Toxicology reports include the following information:
   1. Substances or classes of substances analyzed as part of the toxicology test.
   2. Specimen type.
   3. Report status for positive results (ie, unconfirmed, confirmed or pending confirmation).
   4. Assay cut-off concentration for each drug or drug class.
   5. A statement that drug screening results are to be used only for medical treatment purposes.
   6. A statement that unconfirmed screening results must not be used for non-medical purposes (ie, employee testing).

C. Samples requiring a dilution are automatically requested by the IM. The operator may also program instrument dilutions. The patient result is automatically calculated using the dilution factor. Manual dilutions must be programmed by the operator at the instrument for the dilution factor to be applied.

D. Samples that generate an error code are held at the instrument in exceptions. The error code is reviewed using the online Operations Manual.

E. Instrument result exception error codes that indicate a result is "unable to calculate, result is low" are repeated to verify and reported as "less than". (examples 1056 and 1452)

F. Instrument result exception error codes that indicate a result is "unable to calculate, absorbance exceeded" are diluted to rule out interference in the sample. The result reported will follow the Reportable Range guideline for each assay. (examples 1051 and 1350)

XIV. REFERENCE RANGES:

Refer to **Attachment D.**

XV. REPORTABLE RANGE:

Refer to **Attachment E.**

XVI. LIMITATIONS:

A. Increased levels of lactic acid and LD in postmortem samples may cause falsely elevated ethyl alcohol results. Published data indicate that such elevations are unlikely in living persons.

B. Assay results MUST be used with other clinical data. If assay results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

C. The ARCHITECT System has been validated for its intended use. However, errors can occur due to potential operator errors and ARCHITECT System technology limitations.

XVII. INTERFERING SUBSTANCES:

Refer to **Attachment F** for Interference due to Hemolysis, Lipemia and Icteria. Consult the Product Information sheets for each test for specific information on interferences with endogenous substances and other drugs.

XVIII. REFERENCES:

A. Abbott ARCHITECT System Operation Manual, Abbott Laboratories, Abbott Park, IL. 12-14-2017

B. ARCHITECT System Quick Reference Guide, Abbott Laboratories, Abbott Park, IL 2017

C. Nacca N, et al., Clin Toxicol. 2018; 56:189-92.

D. Nine JS, et al., J Anal Toxicol. 1995; 19:192-6.

Attachments

Abbott Architect Chemistry Attachment A - Clinical Significance

Abbott Architect Chemistry Attachment B - Reagent Reference Guide

Abbott Architect Chemistry Attachment C - Calibrators

Abbott Architect Chemistry Attachment D - Reference Ranges

Abbott Architect Chemistry Attachment E - Reportable Range

Abbott Architect Chemistry Attachment F - Hemolysis, Icteria, Lipemia Interference

Abbott Architect Chemistry Attachment G - Tests by Campus

Abbott Architect Chemistry Attachment H - Specimen Stability

Abbott Architect Chemistry Attachment I - Fluid Reference Guide

Approval Signatures

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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

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Albumin	The quantitative determination of albumin can aid in the diagnosis and management of numerous diseases including those involving the liver and kidneys. It may also be used to assess nutritional status although prealbumin is a better indicator of malnutrition.
A1-Antitrypsin	More than 70 genetic variants of alpha-1-antitrypsin (AAT) have been described. Not all of these are associated with decreased AAT levels or with clinical disease. An individual homozygous for PiZ has about 15% normal AAT and Pi null has no AAT. Such individuals are at significantly increased risk for development of pulmonary emphysema at an earlier age than individuals with a normal AAT phenotype; this process is accelerated by smoking. Development of liver disease may occur in infants (hepatitis and cirrhosis) and in older individuals (chronic hepatitis and cirrhosis). In individuals with a decreased level of AAT, Alpha 1 Antitrypsin Phenotyping is recommended.
ACE	The angiotensin converting enzyme assay is used to aid in the diagnosis of active sarcoidosis. It may be useful for confirmation of Gaucher's disease.
Alk Phos	The quantitative determination of alkaline phosphatase activity aids in the diagnosis and management of liver and bone diseases.
ALT	The quantitative determination of ALT (alanine aminotransferase) aids in the diagnosis and management of liver disease.
Amylase	Amylase measurements aid in the diagnosis and management of pancreatitis (inflammation of the pancreas).
ASO	Streptolysin O is one of several immunogenic exoenzymes produced by Group A, Beta-hemolytic streptococci. An elevated anti-streptolysin O (ASO) titer is usually indicative of a recent infection with a group A streptococci and is a routine part of the diagnosis and management of acute rheumatic fever and acute glomerulonephritis. In the absence of complications or reinfection, antibody levels usually fall to preinfection levels 6-12 months following infection.
AST	The quantitative determination of AST (aspartate aminotransferase) aids in the diagnosis and management of certain types of liver disease. AST is no longer recommended for diagnosis of myocardial infarction.
B2-Microglobulin	This assay is used to evaluate renal disease and to assess prognosis and monitor lymphoproliferative disorders, such as multiple myeloma and chronic lymphocytic leukemia.
BUN	The BUN assay is frequently requested in conjunction with the serum creatinine test for the differential diagnosis of prerenal (cardiac decompensation, water depletion, increases protein catabolism), renal (glomerulonephritis, chronic nephritis, polycystic kidney, nephrosclerosis, tubular necrosis), and postrenal (obstructions of the urinary tract) hyperuremia.
C3 Complement	C3 quantitation is used to detect individuals with congenital C3 deficiencies, or individuals who have depleted their complement levels due to an immunological process. C3 has the highest serum concentration of any complement component. Complement C3 is used as a screening test because it is consumed by activation of either the classical or alternative pathway. Individual assays for C3 and C4 are most useful in monitoring patients with immunologic diseases. Functional assays (e.g., the CH50 test) measure the activity of the entire complement cascade and are more likely to detect inherited deficiencies.
C4 Complement	C4 measurements should be performed whenever a complement activating disease is suspected or whenever hyposynthesis due to inherited deficiency is a possibility. C4 is the second most abundant complement protein in serum. C4 is only used in the classical pathway. Conditions affecting only the alternate pathway will not affect C4 levels. Individual assays for C3 and C4 are most useful in monitoring patients with immunologic diseases. Functional assays (e.g., the CH50 test) measure the activity of the entire complement cascade and are more likely to detect inherited deficiencies.
Calcium	The quantitative determination of calcium aids in the diagnosis and management of a variety of diseases including those involving the parathyroid glands, bone and kidneys.
Ceruloplasmin	Wilson's Disease is an autosomal recessive trait resulting in a copper metabolism disorder. It effects males and females equally. The onset of the disease is commonly seen in late childhood and early adult life. Affected individuals usually have ceruloplasmin levels less than 20 mg/dL. In these patients, free copper accumulates in selected areas of the body and may result in cirrhosis of the liver and central nervous system dysfunctions. These symptoms can improve with treatment. In untreated patients, the disease progresses and is usually fatal. Menke's Disease (also known as "kinky hair" disease) is a sex-linked disease that produces hypoceruloplasminemia. The disease affects only males and is characterized by steely hair, defective cross-linking of collagen and elastin, and neurologic findings. Menke's Disease is usually fatal within 3 years.
Cholesterol	Total cholesterol is used to assess the risk of ASCVD. It is recommended that HDL Cholesterol, non-LDL Cholesterol, LDL Cholesterol and Triglycerides also be obtained in initial screening. Several organizations have issued guidelines for management of dyslipidemias, all aiming to standardize and optimize patient care. The recent ACC/AHA guidelines aim to reduce/prevent heart disease, peripheral vascular disease and stroke by taking into account life style and lipid levels (1). Based on this information an estimate of ASCVD risk can be calculated and a decision on whether or not to treat (e.g. with statins) and modify life style can be made. The ACC/AHA guidelines do not recommend specific cholesterol set-points, but aim for a particular percent decrease in LDL cholesterol. Our lab will continue to use the ATP guideline cut-points in lipid reporting (2). The National Lipid Association also has recommendations that are similar to the ATP III guidelines (3). Total cholesterol may be decreased after acute myocardial infarction (AMI). Assessment of lipid status should therefore be determined within 24 hours of chest pain or 12 weeks following the AMI.
CK	The quantitative determination of CK (creatine kinase) and its isoenzymes aid in the diagnosis and management of myocardial, skeletal, and muscle diseases.
Cl	The quantitation of chloride aids in the diagnosis and treatment of electrolyte and metabolic disorders such as acidosis or alkalosis, dehydration, renal failure and hormone imbalance.
CO2	The CO_2 assay aids in the evaluation of acid-base balance.
Creatinine	The quantitative determination of creatinine aids in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. It is most sensitive in detecting renal impairment when used as part of a Creatinine Clearance test.

CRP	C-reactive protein (CRP) is an acute phase reactant and is used as a sensitive and quantitative measure of the body's acute phase response. CRP is not diagnostic for any specific disease. Increased CRP levels are consistently found in patients with acute bacterial and viral infections, rheumatoid arthritis, acute myocardial infarction, and widespread malignant disease. CRP levels respond to inflammation within 8 hours of onset and peak levels are reached within 24-48 hours. Levels may rise to 2000 times normal levels.CRP levels associated with viral infection, rheumatoid arthritis, and neoplasia are usually 10-40 mg/L. CRP levels of 40 to greater than 300 mg/L are usually associated with acute bacterial infections. Monitoring serum CRP levels aids in the detection and evaluation of post-operative complications associated with inflammation and/ or tissue necrosis. CRP levels evaluated 48-72 hours postoperatively may be 250-350 mg/L. These levels return to normal within one week.
CRP High Sensitivity	In an apparently healthy adult or in the absence of a known inflammatory process, hs-CRP assesses an individual's risk of developing a coronary event, stroke or peripheral vascular disease.
Cystatin C	Cystatin C is a low molecular weight cystein proteinase inhibitor that is produced by all nucleated cells and found in body fluids, including serum. Since it is formed at a constant rate and freely filtered by the kidneys, its serum concentration is inversely correlated with the glomerular filtration rate (GFR); this is, high values indicate low GFRs while lower values indicate higher GFRs similiar to creatinine. Cystatin C can be useful in monitoring GFR in patients where serum cereatinine may be misleading such as very obese, elderly and malnourished patients.
Dbili	The quantitative determination of direct bilirubin is used in the evaluation of liver and biliary disease.
GGT	The quantitative determination of GGT (gamma-glutamyl transferase) aids in the diagnosis and monitoring of hepatobillary disease. GGT is currently the most sensitive enzymatic indicator of liver disease. Normal GGT values are rarely found in the presence of clinically significant hepatic disease.
Glucose	Glucose measurements are used in the diagnosis and management of disorders of carbohydrate metabolism; these include diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell tumors.
Haptoglobin	Haptoglobin binds to hemoglobin released into the circulation by intravascular hemolysis. Haptoglobin is an acute phase reactant. Serial assays are used to detect and monitor hemolytic states. Haptoglobin is decreased in diseases associated with intravascular hemolysis. In severe hemolysis, haptoglobin may be totally depleted, requiring up to 1 week to return to normal. In chronic hemolytic states such as hemoglobinopathies and mechanical heart valves, there may be a steady decline in haptoglobin levels. In these conditions, serial assays provide a better index of ongoing hemolysis than a single haptoglobin value. Increased serum haptoglobin levels are present in infection, neoplasia, and other inflammatory conditions characterized by tissue injury and repair
HDL Chol	The quantitative determination of HDL (high-density lipoprotein) cholesterol aids in the diagnosis and treatment of lipid disorders. It should be used in the risk assessment of coronary artery disease (CAD). Low levels of HDL cholesterol are associated with an increased risk of CAD.
IgA	Selective IgA deficiency is a primary immunodeficiency disorder characterized by reduced production of IgA with recurrent respiratory and gastrointestinal infections. Selective IgA deficiency can result from congenital intrauterine infection with rubella virus, *Toxoplasma gondii*, or cytomegalovirus. A transient IgA deficiency may result following the treatment with penicillamine of Wilson's disease. Most patients with selective IgA deficiencies are asymptomatic. Symptomatic patients usually present with recurrent ear infections, sinusitis, pneumonia, diarrhea, asthma, autoimmune diseases and/or allergies. Administration of blood products containing IgA can cause some IgA deficient patients to develop antibodies against IgA. If an anti-IgA antibody develops, a massive allergic reaction can result during blood or plasma transfusions.
IgG	IgG levels can be used to evaluate humoral immunity and aids in the diagnosis of conditions associated with IgG excess or depression. IgG can cross the placenta. IgG antibodies are the most important and persistent antibodies of the secondary immune response.
IgM	IgM levels can be used to evaluate humoral immunity and to assist in the diagnosis of conditions associated with IgM excess or depression. IgM is the first antibody to appear in a primary antibody response. IgM does not cross the placenta. Increased IgM levels in the newborn are associated with intrauterine infections.
Iron	This assay is used in the evaluation of iron deficiency, hemochromatosis and to verify acute iron poisoning.
K	The quantitation of potassium is used to monitor electrolyte balance.Pseudohyperkalemia: If an increase in platelets or leukocytes is suspected as a cause of hyperkalemia, a heparin tube should be obtained for plasma potassium.
LD	Lactate dehydrogenase is present in multiple cells and tissue types and therefore its utility in patient diagnosis is questionable. It is useful in the assessment of in-vivo hemolysis and hematologic disorders (benign and malignant) conditions in which LD is often increased. LD is also increased following myocardial infarction, pulmonary and renal cortical infarction, liver disease, skeletal muscle disease, and many other conditions. Use of more specific enzymes and protein markers is preferable to LD in the diagnosis of myocardial infarction (use Troponin or CK-MB), skeletal muscle (use CK) and liver disease.
LDL Chol (Direct)	This direct quantitative determination of LDL cholesterol aids in the diagnosis and management of coronary atherosclerosis. Several organizations have issued guidelines for management of dyslipidemias, all aiming to standardize and optimize patient care. The recent ACC/AHA guidelines aim to reduce/prevent heart disease, peripheral vascular disease and stroke by taking into account life style and lipid levels. Based on this information an estimate of ASCVD risk can be calculated and a decision on whether or not to treat (e.g. with statins) and modify life style can be made. The ACC/AHA guidelines do not recommend specific cholesterol set-points, but aim for a particular percent decrease in LDL cholesterol. Our lab will continue to use the ATP guideline cut-points in lipid reporting. The National Lipid Association also has recommendations that are similar to the ATP III guidelines.
Lipase	This assay aids in the diagnosis of patients suspected of having acute pancreatitis.

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Lipoprotein A1	Elevated levels of Lp(a) indicate a major risk for the development of atherosclerosis and coronary heart disease, independent of LDL-cholesterol levels. The wide differences in lipoprotein(a) levels seen among individuals are largely due to hereditary factors and cannot be controlled by dietary or lifestyle changes. Nevertheless, the identification of individuals at risk can be useful in alerting them to the need to eliminate or control other high risk factors.
Magnesium	The quantitation of magnesium aids in the investigation of unexplained hypocalcemia, in the management of patients following cardiac surgery or those with cardiac arrhythmias, and in the management of patients being treated for pre-eclampsia or eclampsia. An association between severe hypomagnesemia and aminoglycoside therapy has been described.
Na	The quantitation of sodium is used to monitor electrolyte balance.
Phosphorus	Measurement of inorganic phosphorus aids in the diagnosis and management of various disorders, including those involving the parathyroid gland, kidney, bone, and vitamin D metabolism.
PLACA	Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) has been shown to be an independent inflammatory marker of cardiovascular risk and events. It is produced by macrophages in response to the presence of oxidized lipids and circulates primarily in association with low-density lipoprotein particles (LDL). Whereas hsCRP detects inflammation that is either part of atherosclerosis or some other systemic or localized process, Lp-PLA2 is much more specific for vascular inflammation and appears to be a marker of unstable atherosclerotic plaques. In the West of Scotland Coronary Prevention Study (WOSCOPS) (2), there was a two-fold risk of CHD in individuals in the highest quintile compared to the lowest quintile and in the Atherosclerosis Risks in Communities Study (ARIC) (3), there was almost a two-fold risk of ischemic stroke in individuals with an increased Lp-PLA2 level.
Pre-Albumin	Serum prealbumin levels are used as an index of subclinical or marginal protein-calorie malnutrition, as an indicator of response to total parenteral nutrition (TPN), a marker of nutritional status in premature infants, and as an index of liver function in hepatobiliary disease.
Rheumatoid Factor	Rheumatoid factor assay is one of the most frequently requested tests in the clinical investigation of patients with joint symptoms. Rheumatoid factor (RF) is usually an IgM autoantibody that reacts with the Fc portion of IgG. In the presence of pathogen-specific IgG antibodies, IgM RF can produce false-positive results in IgM assays. RF is not a screening test. The test performs poorly when applied to the general population.
Tbili	Total Bilirubin, Serum. The quantitative determination of bilirubin aids in the evaluation of liver disease, in the detection of hemolytic anemia, and in the evaluation of jaundice. Bilirubin, Cord Blood: Cord blood bilirubin may be a useful indicator of developing jaundice in newborns and a useful predictor of significant hyperbilirubinemia in the neonate.
Total Protein	Total protein measurements aid in the assessment of nutritional status (see Prealbumin) and may be useful in the diagnosis and management of a variety of diseases involving the liver, kidney, and bone marrow.
Transferrin	Transferrin functions as the principal plasma protein responsible for the transport of iron. Transferrin binds and transports iron and serves as a negative acute phase reactant (levels decrease during inflammatory processes). Transferrin levels in serum aid in the diagnosis of iron deficiency anemia, malnutrition, acute inflammation, infection, assessment of renal function, and red blood cell disorders. Serum transferrin concentration increases in iron deficiency anemia, pregnancy, and patients taking estrogens. Decreased transferrin levels are associated with chronic infections, malignancy, iron overload, hemolytic anemia, hemochromatosis, sickle cell disease, atransferrinemia, renal disease, and hepatic failure. Atransferrinemia is a rare congenital disorder. Patients with this disorder have very low levels of plasma transferrin. They also have iron overload and severe anemia that results from their inability to mobilize the body's iron stores.
Triglycerides	Triglyceride measurements aid in the diagnosis and management of patients with primary and secondary lipid disorders (e.g., diabetes mellitus, renal disease, liver obstruction, hypothyroidism).
Uric Acid	Uric acid measurements aid in the diagnosis and management of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs. It is recommended that patients being treated for gout maintain a uric acid level of less than 6 mg/dL.
Ammonia	The diagnostic utility of ammonia measurements is limited. The test is used mainly in the diagnosis of urea cycle defects and in the detection of Reye's syndrome. Levels of ammonia do not correlate well with CNS changes in end-stage liver disease.
B-OH Butyrate	This assay aids in the diagnosis and monitoring of therapy for diabetic ketoacidosis. This assay may also aid in the diagnosis of any patient presenting to the emergency room with documented hypoglycemia, acidosis, alcohol ingestion, or an unexplained increase in the anion gap and in the investigation of inborn errors of metabolism.
Ethanol	This assay is used to document prior consumption or administration of ethanol. Ethanol is the single most important abused substance in the U.S. Ethanol is found in beer, wine, and other liquors. Ethanol depresses cerebral functions similar to general anesthetics. Symptoms of ethanol abuse may include impaired thought, clouded judgment, and changed behavior. Blood ethanol levels correlate directly with the degree of intoxication.
Lactate	This assay aids in the evaluation of metabolic acidosis, regional or diffuse tissue hypoperfusion, hypoxia, shock, congestive heart failure, dehydration, complicated postoperative state, ketoacidosis or nonketotic acidosis in diabetes mellitus, patients with infections, inflammatory states, certain myopathies, acute leukemia and other neoplasia, enzyme defects, glycogen storage disease (type1), thiamine deficiency and hepatic failure.
Uric Acid Rasburicase	In patients being treated with Rasburicase (Elitek), "Uric Acid Rasburicase" should be ordered for 3 days following drug administration. This recommendation is based on the drug's half-life and the expected duration of activity. Rasburicase catalyzes the oxidation of uric acid into an inactive and soluble metabolite. It is used for prophylaxis and treatment of chemotherapy-induced or spontaneous acute tumor lysis syndrome. Rasburicase can cause spuriously low plasma uric acid levels if the specimen is transported or stored at room temperature (20-26°C or 68-78.8°F) or if processing is delayed. Uric Acid Rasburicase differs from Uric Acid in the collection and handling of the specimen. Transporting the specimen on ice and running it STAT helps to minimize (but not necessarily completely eliminate) the artifactual effects of rasburicase. Uric acid levels should be ordered in this way only when rasburicase has been administered to a patient.

Peritoneal Fluid	
Albumin	A serum ascites albumin gradient greater than or equal to 1.1 g/dL is consistent with portal hypertension from causes such as cirrhosis, congestive heart failure, or portal vein thrombosis. A low gradient (less than 1.1 g/dL) occurs in conditions such as peritoneal carcinomatosis, peritoneal tuberculosis, pancreatitis, serositis, and nephrotic syndrome. In the past a value of greater than or equal to 1.1 g/dL was interpreted as a transudate, and if less than 1.1 g/dL the fluid was interpreted as an exudate.
Amylase	Useful initially, in the classification of an effusion as an exudate or a transudate.
Tbili	Elevated body fluid bilirubin is suggestive of an exudative fluid. This testing should be performed in conjunction with other testing including serum bilirubin analysis, body fluid/serum protein ration, body fluids/serum lactate dehydrogenase ratio, and serum lactate dehydrogenase. Determination of body fluid bilirubin concentration can aid in the distinction between a transudative and an exudative fluid. Bilirubin values tend to be higher in exudates than in transudates, although there is some overlap between groups. However, a ratio of body fluids to serum bilirubin has been reported to identify exudative body fluids with sensitivity, specifically, positive predictive accuracy, and absolute accuracy equivalent to that obtained using Light's criteria for an exudative pleural fluid (pleural/serum protein ratio greater than 0.5, pleural/serum lactate dehydrogenase ratio greater than 0.6, and serum lactate dehydrogenase greater than 200 U/L).
Cholesterol	Peritoneal fluid cholesterol determination can distinguish cirrhotic versus malignant ascites.
Creatinine	Measurement of creatinine is useful to differentiate between peritoneal fluid and urine. Elevated peritoneal fluid creatinine, in association with normal serum creatinine, suggests urinary bladder leakage or rupture.
Glucose	Glucose measurement in body fluid may be useful with other laboratory tests to evaluate effusions. Decreased concentrations are associated with bacterial infections, inflammation such as rheumatoid arthritis, and occasionally malignancy.
LD	Measuring LD in fluid aspirated from a pleural effusion (or pericardial effusion) can help in the distinction between exudates (actively secreted fluid, e.g. due to inflammation) and transudates (passively secreted fluid, due to a high hydrostatic pressure or a low oncotic pressure). The most reliable method for differentiating between transudates and exudates is the simultaneous analysis of fluid and serum for lactic dehydrogenase (LD) and total protein level.
Total Protein	Total Protein Interpretation: Measurement of total protein in body fluids other than blood, urine, or cerebrospinal fluid is usually done to differentiate an inflammatory fluid collection (exudate) from one that is non-inflammatory (transudate). In pericardial, peritoneal, pleural, and synovial fluids, 3 g/dL is usually taken as the cut-off value for differentiating transudates from exudates. Some authors use a lower cut-off of 2.5 g/dL.Some references suggest using a ratio of fluid to serum protein to differentiate transudate from exudate. Protein is just one of several markers that can be used for differentiating transudates from exudates. Low total protein is seen in patients with cirrhosis of the liver when ascites develops late in the disease. Patients with a low value, below 1.5 g/dL, are at greater risk of developing spontaneous bacterial peritonitis. Knowing that the concentration is low has some prognostic value, although it should not be a reason for beginning prophylactic antibiotic therapy.
Triglycerides	Peritoneal fluid triglyceride determination can distinguish cirrhotic versus malignant ascites

Amniotic Fluid	
Glucose	The following criteria is/are considered to be predictive of a positive amniotic fluid culture: 1) Positive gram stain for bacteria or 2) WBC count >30 cells/mm3 and 3) Low amniotic fluid glucose less than 15 mg/dL. Laboratory studies on amniotic fluid should be performed on non-bloody fluid obtained by amniocentesis only.

Pleural Fluid	
Albumin	Serum albumin/pleural fluid albumin gradient of less than or equal to 1.2 g/dL is consistent with exudate.
Amylase	Useful initially, in the classification of an effusion as an exudate or a transudate.
Tbili	Pleural fluid bilirubin/serum bilirubin ratio of greater than or equal to 0.60 is consistent with exudate.
Cholesterol	Fluid cholesterol/serum cholesterol ratio greater than or equal to 0.3 or fluid cholesterol greater than 45 mg/dL is consistent with exudate.
Glucose	Pleural fluid glucose of less than 60 mg/dL or pleural fluid glucose/serum glucose ratio of less than 0.5 is abnormal. Abnormal pleural fluid glucose is seen in rheumatoid pleuritis and parapneumonic exudates. It can also be seen in malignancy, tuberculosis, SLE, and esophageal rupture.
LD	Pleural fluid LD/serum LD ratio of greater than or equal to 0.60 or pleural fluid LD greater than or equal to 2/3^{ds} the upper limit of normal serum LD level is consistent with exudate. Pleural fluid LD/serum LD ratio of less than 0.60 or pleural fluid LD less than or equal to 2/3^{ds} the upper limit of normal serum LD level is consistent with transudate.
Total Protein	Pleural fluid TP/serum TP ratio of greater than 0.5 or pleural fluid total protein level greater than 3.0 g/dL is consistent with exudate. Pleural fluid TP/serum TP ratio of less than or equal to 0.5 or pleural fluid total protein level less than or equal to 3.0 g/dL is consistent with transudate. Using total protein alone misclassifies exudates and transudates by approximately 30%. Sensitivity and specificity increases to 98% and 80%, respectively, when using both total protein and LD criteria for classifying exudates or transudates.
Triglycerides	Pleural fluid triglyceride levels greater than or equal to 110 mg/dL is indicative of chylous effusion. Pleural fluid triglyceride level less than 50 mg/dL is indicative of non-chylous effusion. Levels between 50-109 mg/dL are equivocal.

Dialysate Fluid	
Creatinine	Results of Creatinine, Glucose, and Urea Nitrogen are used by clinical staff in calculations to assess the adequacy of peritoneal dialysis.
Glucose	Results of Creatinine, Glucose, and Urea Nitrogen are used by clinical staff in calculations to assess the adequacy of peritoneal dialysis.
Urea Nitrogen	Results of Creatinine, Glucose, and Urea Nitrogen are used by clinical staff in calculations to assess the adequacy of peritoneal dialysis.

Pancreatic Fluid	
Amylase	Testing is used to determine whether a pancreatic cyst is likely to be benign or malignant. However these results cannot be used in isolation and should be used in conjunction with clinical information, imaging studies, and cytology.

Pericardial Fluid	
Glucose	Biochemical analysis of pericardial fluid is of limited clinical value in most cases. Light's criteria, originally established for pleural effusions, have been shown to classify nearly all pericardial fluids as exudates regardless of etiology. (Am K Cardiol;/2007;99(9):Heart.2020;106(7):541.)
LD	
Total Protein	

Urine	
Amylase	The urinary amylase assay aids in the diagnosis of pancreatitis, pancreatic pseudocyst and macroamylasemia.
Calcium	24 hour urine calcium reflects intake, rates of intestinal calcium absorption, bone resorption and renal loss. Those processes relate to parathyroid hormone and vitamin D levels. Urinary calcium measurements are most useful for evaluation of patients with renal stones or a possible diagnosis of familial hypocalciuric hypercalcemia.
Chloride	Urinary chloride measurements aid in the differentiation of causes of metabolic alkalosis and help classify them as chloride responsive or unresponsive.
Creatinine	This assay aids in the diagnosis and management of renal diseases (when done as part of a Creatinine Clearance test), in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Glucose	This assay aids in the evaluation of glucosuria and renal tubular defects. It is rarely needed in the management of diabetes mellitus.
Magnesium	Magnesium measurements aid in the diagnosis and management of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium). Urine magnesium is measured as part of the Stone Former Panel and is useful in assessing the likelihood of stone formation.
Micro Albumin	Microalbuminuria is an amount of albumin in the urine above normal (10 mg/L) but below that detected by dipsticks for urinary protein (greater than 30 mg/dL). Microalbuminuria has an important predictive value in determining diabetic patients at risk of developing nephropathy. Microalbuminuria may also be caused by poor metabolic regulation, physical exercise, newly diagnosed diabetes, hypertension, and non-diabetic renal or systemic disease.
Phosphorus	Inorganic phosphorus measurements aid in the diagnosis and management of various disorders, including parathyroid gland and kidney diseases, vitamin D imbalance and kidney stones.
Potassium	Urinary potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
Sodium	Urinary sodium measurements aid in the evaluation of patients with acute oliguria (low urine output), hyponatremia, and volume depletion.
Total Protein	Urinary protein measurements aid in the diagnosis and management of primary diseases involving the kidney and diseases which may secondarily involve the kidney, such as collagen-vascular disease, multiple myeloma, amyloidosis, metal poisoning, diabetes mellitus, pre-eclampsia, or eclampsia.
Urea (UUN)	Urine urea nitrogen is performed as part of the Stone Former Workup to evaluate a patient for the likelihood of renal calculi formation.
Uric Acid	Uric acid measurements aid in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation, or other wasting conditions, and of patients receiving cytotoxic drugs. It is also part of the Stone Former Workup and is useful in assessing the likelihood of stone formation.

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CSF	
CSF Glucose	Evaluation of meningitis, neoplastic involvement of meninges, and other neurological disorders.
CSF Lactate	Evaluation of meningitis, neoplastic involvement of meninges, and other neurological disorders.
CSF LD	Evaluation of meningitis, neoplastic involvement of meninges, and other neurological disorders.
CSF Protein	Evaluation of meningitis, neoplastic involvement of meninges, and other neurological disorders.
Therapeutic Drugs	
Acetaminophen	Acetaminophen is an analgesic, antipyretic drug lacking in significant anti-inflammatory activity. This assay is used to monitor the therapeutic drug level and evaluate the toxicity of acetaminophen. Serum concentration and half-life are the only way to assess the degree of intoxication in the early stages since other liver function studies (bilirubin and liver function enzymes) will not show clinically significant increases until after tissue damage has occurred, at which point therapy is ineffective.
Amikacin	Amikacin is a semisynthetic aminoglycoside antibiotic with a broad spectrum of activity against gram-negative bacteria. This assay is used to monitor the therapeutic drug level and evaluate the toxicity of amikacin.
Carbamazepine	Carbamazepine is an anticonvulsant drug used in the treatment of generalized and partial seizures. This assay aids in monitoring carbamazepine levels to ensure appropriate therapy.
Digoxin	This assay is used to monitor the therapeutic drug level and evaluate the toxicity of digoxin. Digoxin is a cardiac glycoside that is commonly prescribed to treat congestive heart failure.
Gentamicin	Gentamicin is an aminoglycoside antibiotic which exhibits high potency and a broad spectrum bacterial action primarily against gram-negative organisms. Gentamicin is associated with renal and ototoxicity upon extended use. Therapeutic monitoring is advantageous particularly in patients with diminished renal function.
Lithium	This assay is used to monitor the therapeutic drug level and evaluate the toxicity of lithium.
Phenobarbital	Phenobarbital is an anti-convulsant and sedative-hypnotic drug. It is used for the treatment of epilepsy, particularly for controlling focal motor or sensory seizures and grand mal seizures. It is frequently co-administered with phenytoin for the control of complex seizure disorders and with valproic acid for complex partial seizures. Monitoring the serum concentrations of phenobarbital has been shown to improve patient therapy by aiding the physician in adjusting their dosage. Phenobarbital has a narrow therapeutic index and wide inter-individual variability in the rate of metabolism and clearance. This assay is used to monitor the therapeutic drug level and evaluate the toxicity of phenobarbital.
Phenytoin	Phenytoin is an anticonvulsant drug. It is occasionally used as an antiarrhythmic. In the treatment of epilepsy, phenytoin is indicated for grand mal epilepsy, cortical focal seizures and temporal lobe epilepsy. Phenytoin has a narrow therapeutic index and a wide interindividual variability in the rate of metabolism and clearance necessitating the determination of blood levels for patients receiving therapy. This assay is used to monitor the therapeutic drug level and evaluate the toxicity of phenytoin.
Salicylate	The salicylate assay aids in the diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to insure appropriate therapy. Salicylates are a group of compounds used as analgesics, antipyretics and anti-inflammatory agents. Acetylsalicylic acid (aspirin) is the most commonly used salicylate. Salicylates are readily available over-the-counter and most salicylate therapy is the result of patient self-medication. For this reason, salicylates are often seen in overdose cases. Salicylate poisoning is seldom fatal, but causes side effects ranging from nausea, vomiting and tinnitus to fever, lethargy and coma. Prompt recognition and management are necessary to avoid serious consequences.
Theophylline	Theophylline is a naturally occurring compound with bronchodilator effects. It is used in the treatment of bronchospasm associated with bronchial asthma, chronic bronchitis and pulmonary emphysema. This assay is used to monitor the therapeutic drug level and evaluate the toxicity of theophylline. Due to the drug's narrow therapeutic range and the wide personal variation in the rate of metabolism and clearance, essentially every patient taking theophylline should have their serum levels monitored.
Tobramycin	Tobramycin is an aminoglycoside antibiotic. Tobramycin has a narrow therapeutic index which makes its use hazardous, especially in patients with impaired renal function. Accurate monitoring of the serum level in such patients is mandatory. This assay aids in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.
Valproic Acid	Valproic acid is a broad-spectrum anticonvulsant drug used alone to treat simple and complex absence seizures and in combination with other anticonvulsant drugs for control of generalized seizures that include absence seizures. This assay is used to monitor the therapeutic drug level and evaluate the toxicity of valproic acid.
Vancomycin	Vancomycin is a glycopeptide antibiotic which is bactericidal against many gram-positive and some gram-negative cocci. It is used to treat severe staphylococcal infections in patients who cannot receive or who have failed to respond to the penicillins and cephalosporins. Vancomycin should be used with care due to its potential nephrotoxic and ototoxic effects. This assay aids in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.
Methotrexate	This assay is used to monitor the therapeutic drug level and evaluate the toxicity of methotrexate. Methotrexate is an antineoplastic agent. It is used in the treatment of malignancies with rapid cell proliferation such as acute lymphoblastic leukemia, choriocarcinoma, trophoblastic tumors in women, and carcinomas of the breast, tongue, pharynx, and testis. It is also indicated in the treatment of severe psoriasis and adult rheumatoid arthritis.

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DAU

Clinical Significance

Amphetamine/ Methamphetamine	Amphetamine and methamphetamine are central nervous system stimulants. They are usually administered orally or by intravenous injection. These drugs are prescribed for treatment of obesity, narcolepsy, hypotension, attention deficit disorder, and hyperactivity disorder. Because of their stimulant effects, the drugs are commonly sold illicitly and abused. This assay is used to aid in the diagnosis and treatment of amphetamine and/or methamphetamine use or abuse.
Barbiturate	This assay is used to aid in the diagnosis and treatment of barbiturate use or abuse. Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. The legal availability of barbiturates has declined but they remain frequently abused sedatives or hypnotic drugs. The most commonly abused barbiturates are the short-acting compounds such as secobarbital, pentobarbital and amobarbital. Tolerance to these drugs can develop from chronic use and death may occur from overdose.
Benzodiazepine	This assay is used to aid in the diagnosis and treatment of benzodiazepine use or abuse. Benzodiazepines are central nervous system depressants composed of over 20 compounds. They are used clinically as sedatives, hypnotics, anxiolytics, muscle relaxants, antiepileptics, and in the treatment of alcohol withdrawal. Benzodiazepines are extensively metabolized with half-lives ranging from 1 to 100 hours. Urine levels vary due to each patient's metabolic and excretion rates.
Cannabinoid	This assay is used to aid in the diagnosis and treatment of cannabinoid use or abuse. The primary psychoactive component of marijuana is delta-9-tetra-hydrocannabinol (THC). The THC concentration determines the potency of the marijuana. THC primarily affects the cardiovascular and central nervous systems. There is no reliable method for predicting the degree of impairment from cannabinoid concentrations measured in urine at this time.
Cocaine	Cocaine is a frequently abused drug. The drug is administered by nasal insufflation, intravenous injection or in the free base form as smoke inhalation. The urinary elimination of cocaine and its metabolite begins within 20 minutes of its intranasal administration. This assay is used to aid in the diagnosis and treatment of cocaine use or abuse.
Methadone	Methadone is a synthetic narcotic analgesic that is similar to morphine. Methadone is commonly prescribed as the drug of choice in the maintenance treatment of heroin addicts. Patients on methadone therapy are routinely screened for methadone as a measure of compliance. This assay is used to aid in the diagnosis and treatment of methadone use or abuse.
Opiate	Opiates act on several sites of the central nervous system. Their use results in analgesia, drowsiness, mood changes and some mental clouding. This assay is used to aid in the diagnosis and treatment of opiate use or abuse.
Phencyclidine	Phencyclidine (PCP) is a drug of abuse. PCP acts as a stimulant, depressant, hallucinogenic and analgesic. It can be self-administered by smoking, nasal insufflation, intravenous injection or by oral ingestion. This assay is used to aid in the diagnosis and treatment of phencyclidine use or abuse.
Fentanyl	Fentanyl is a synthetic narcotic analgesic of high potency and short duration of action. It may be administered by injection or is available as a transdermal patch for the management of chronic pain.
Oxycodone	Oxycodone is a semi-synthetic narcotic analgesic. Oxycodone can produce drug dependence and tolerance may develop with repeated administration.

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Assay	Method	Sample Type	Reagent On-board Stability	Reagent Prep	Calibrator	Calibration Frequency	Reagent Storage
General Chemistry							
Albumin BCG	Bromocresol Green	Serum or Li Heparin	42 days	Liquid Ready to Use	Multiconstituent	41 days	RT
Alkaline Phosphatase	Para-nitrophenol Phosphate Enzymatic	Serum or Li Heparin	8 days	Liquid Ready to Use	Internal Water Blank Cal Factor	8 days	2°-8°C
ALT	NADH	Serum or Li Heparin	30 days	Liquid Ready to Use	Internal Water Blank Cal Factor	27 days	2°-8°C
Ammonia	Glutamate Dehydrogenase	EDTA Plasma	15 days	Liquid Ready to Use	Calibrator supplied with reagent	24 hours	2°-8°C
Amylase	CNPG3 Substrate	Serum, Li Heparin, Urine	19 days	Liquid Ready to Use	Internal Water Blank Cal Factor	19 days	2°-8°C
AST	NADH	Serum or Li Heparin	30 days	Liquid Ready to Use	Internal Water Blank Cal Factor	30 days	2°-8°C
B-OH Butyrate	Stanbio	Serum or Li Heparin	30 days	Ready to Use	BHBT Calibrator	14 days	2°-8°C
Bilirubin, Direct	Diazo Reaction	Serum or Li Heparin	28 days	Liquid Ready to Use	Bilirubin Calibrator	14 days	2°-8°C
Bilirubin, Total	Diazonium Salt	Serum or Li Heparin	21 days	Liquid Ready to Use	Bilirubin Calibrator	14 days	2°-8°C
Calcium	Arsenazo III Dye	Serum, Li Heparin, Urine	30 days	Liquid Ready to Use	Multiconstituent	30 days	RT
Chloride	indirect potentiometry	Serum, Li Heparin, Urine	ICT Dil 14 days	Liquid Ready to Use	ICT Serum and Urine Calibrator	24 hours	RT
Potassium	indirect potentiometry	Serum, Li Heparin, Urine	ICT Dil 14 days	Liquid Ready to Use	ICT Serum and Urine Calibrator	24 hours	RT
Sodium	indirect potentiometry	Serum, Li Heparin, Urine	ICT Dil 14 days	Liquid Ready to Use	ICT Serum and Urine Calibrator	24 hours	RT
Cholesterol	Enzymatic	Serum or Li Heparin	30 days	Liquid Ready to Use	Multiconstituent Calibrator	30 days	2°-8°C
CK	NAC (N-acetyl-L-cysteine)	Serum or Li Heparin	30 days	Liquid Ready to Use	Internal Water Blank Cal Factor	30 days	2°-8°C
CO2	PEP Carboxylase	Serum or Li Heparin	14 days	Liquid Ready to Use	Carbon Dioxide Calibrator	14 days	2°-8°C
Creatinine	Kinetic Alkaline Picrate	Serum, Li Heparin, Urine	5 days	Liquid Ready to Use	Multiconstituent Calibrator	5 days	RT
Creatinine Ez	Enzymatic	Serum, Li Heparin	30 days	Liquid Ready to Use	Clin Chem Cal	7 days	2°-8°C
GGT	L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	Serum or Li Heparin	27 days	Liquid Ready to Use	Internal Water Blank Cal Factor	27 days	2°-8°C
Glucose	Hexokinase/G-6-PDH	Serum, Li Heparin, Urine, CSF	30 days	Liquid Ready to Use	Multiconstituent Calibrator	30 days	2°-8°C
HDL, Ultra	Accelerator Selective Detergent	Serum or Li Heparin	28 days	Liquid Ready to Use	Lipid Multiconstituent Calibrator	28 days	2°-8°C
Iron	Ferene	Serum or Li Heparin	60 days	Liquid Ready to Use	Multiconstituent Calibrator	14 days	2°-8°C
Lactic Acid	Lactic Acid to Pyruvate	sodium fluoride plasma	30 days	Liquid Ready to Use	Multiconstituent Calibrator	30 days	2°-8°C
LD	Lactate to Pyruvate	Serum or Li Heparin	30 days	Liquid Ready to Use	Internal Water Blank Cal Factor	30 days	2°-8°C
LDL Direct	Measured, Liquid Selective Detergent	Serum or Li Heparin	28 days	Liquid Ready to Use	Lipid Multiconstituent Calibrator	28 days	2°-8°C

Lipase	Quinone Dye	Serum or Li Heparin	11 days	1. Pour contents of R1 into R1A container and mix by gentle inversion until dissolved. 2. Pour contents of R1A back into R1 cartridge and mix again by gentle inversion. R2 reagent is liquid ready to use.	Lipase Calibrator	11 days	2°-8°C
Magnesium	Enzymatic	Serum, Li Heparin, Urine	30 days	Liquid Ready to Use	Multiconstituent Calibrator	30 days	2°-8°C
Phosphorus	Phosphomolybdate	Serum, Li Heparin, Urine	65 days	Liquid Ready to Use	Multiconstituent Calibrator	41 days	RT
Total Protein	Biuret	Serum or Li Heparin	23 days	Liquid Ready to Use	Multiconstituent Calibrator	23 days	RT
Triglyceride	Glycerol Phosphate Oxidase	Serum or Li Heparin	42 days	Liquid Ready to Use	Multiconstituent Calibrator	41 days	2°-8°C
Urea Nitrogen	Urease	Serum, Li Heparin, Urine	25 days	Liquid Ready to Use	Multiconstituent Calibrator	7 days/ required with each new cartridge	2°-8°C
Uric Acid	Uricase	Serum, Li Heparin, Urine	60 days	Liquid Ready to Use	Multiconstituent Calibrator	60 days	2°-8°C
Urine/CSF Protein	Benzethonium chloride	Urine, CSF	41 days	Liquid Ready to Use	Urine/CSF Protein Calibrator	41 days	RT

Special Proteins

A1-Antitrypsin	Immunoturbidimetric	Serum	35 days	Ready to Use	Proteins	30 days	2°-8°C
ASO	Immunoturbidimetric	Serum	35 days	Ready to Use Invert to Mix	ASO Calibrator	35 days	2°-8°C
Beta 2- Microglobulin	Immunoturbidimetric	Serum	30 days	Ready to Use Invert to Mix	B2 Microglobulin Calibrator	31 days	2°-8°C
Ceruloplasmin	Immunoturbidimetric	Serum	60 days	Liquid Ready to Use	Multigent Plasmaproteins Cal	10 days	2°-8°C
Complement 3	Immunoturbidimetric	Serum	57 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	57 days	2°-8°C
Complement 4	Immunoturbidimetric	Serum	57 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	57 days	2°-8°C
CRP Vario (Wide Range)	Immunoturbidimetric	Serum	60 days	Liquid Ready to Use	Multigent CRP Calibrator WR	15 days	2°-8°C
CRP Vario (Ultrasensitive)	Immunoturbidimetric	Serum	60 days	Liquid Ready to Use	Multigent CRP Calibrator HS	15 days	2°-8°C
Cystatin C	Immunoturbidimetric	Serum, Li Heparin	63 days	Liquid Ready to Use	Cystatin C Calibrator	28 days	2°-8°C
Haptoglobin	Immunoturbidimetric	Serum	57 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	57 days	2°-8°C
Immunoglobulin A	Immunoturbidimetric	Serum	28 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	25 days	2°-8°C
Immunoglobulin G	Immunoturbidimetric	Serum	23 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	23 days	2°-8°C
Immunoglobulin M	Immunoturbidimetric	Serum	57 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	57 days	2°-8°C
Lipoprotein A1	Immunoturbidimetric	Serum	35 days	Liquid Ready to Use	Quantia Lp(a) Calibrator	30 days	2°-8°C

Microalbumin	Immunoturbidimetric	Urine	28 days	Liquid Ready to Use	Microalbumin Calibrators	28 days	2°-8°C
Prealbumin	Immunoturbidimetric	Serum	57 days	Liquid Ready to Use	Prealbumin Calibrator	57 days	2°-8°C
Rheumatoid Factor (RF)	Immunoturbidimetric	Serum	30 days	Ready to Use Invert to Mix	Rheumatoid Factor Calibrator	60 days	2°-8°C
Transferrin	Immunoturbidimetric	Serum or Li Heparin	57 days	Liquid Ready to Use	Specific Proteins Multiconstituent Calibrator	57 days	2°-8°C
Therapeutic Drugs							
Amikacin	PETINIA	Non SST Serum	54 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	54 days	2°-8°C
Carbamazepine	PETINIA	Non SST Serum	45 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	7 days	2°-8°C
Digoxin	PETINIA	Serum, Non SST preferred. SST acceptable	60 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	60 days	2°-8°C
Gentamicin	PETINIA	Non SST Serum	55 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	28 days	2°-8°C
Lithium	Colorimetric	SST Serum preferred, Non SST acceptable	18 days	Liquid Ready to Use	Clin Chem Cal	5 days	2°-8°C
Phenobarbital	PETINIA	Non SST Serum	40 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	14 days	2°-8°C
Phenytoin	EIA	Non SST Serum	40 days	Liquid Ready to Use	TDM Multiconstituent Calibrator	7 days	2°-8°C
Theophylline	EIA	Serum, Non SST preferred. SST acceptable	40 days	Liquid Ready to Use	TDM Multiconstituent Calibrator	7 days	2°-8°C
Tobramycin	PETINIA	Non SST Serum	32 days	Ready to Use Invert to Mix	Tobramycin Calibrator	7 days	2°-8°C
Valproic Acid	PETINIA	Serum, Non SST preferred. SST acceptable	54 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	27 days	2°-8°C
Vancomycin	PETINIA	Serum, Non SST preferred. SST acceptable	45 days	Ready to Use Invert to Mix	TDM Multiconstituent Calibrator	45 days	2°-8°C
Drugs of Abuse/Toxicology							
Acetaminophen	Enzymatic/Colorimetric	Non SST Serum	8 days	Liquid Ready to Use R1 reagent one bottle, R2 reagent 2 bottles poured into 20 mL wedges	Acetaminophen Calibrator	24 hours	2°-8°C
Amphet/Meth	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and DOA Cal #1	13 days	2°-8°C
Barbiturates	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and DOA Cal #2	13 days	2°-8°C
Benzodiazepines (Urine)	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and DOA Cal #1, 2, 3, 4	7 days	2°-8°C
Cannabinoids	EIA	Urine	30 days	Liquid Ready to Use	DOA Neg Cal and THC 50	13 days	2°-8°C
Cocaine	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and DOA Cal #2	13 days	2°-8°C
Methadone	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and DOA Cal #2	10 days	2°-8°C
Opiates	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and Opiate 300	13 days	2°-8°C
Phencyclidine	EIA	Urine	56 days	Liquid Ready to Use	DOA Neg Cal and DOA Cal #2	14 days	2°-8°C
Salicylate	Enzymatic/Colorimetric	Non SST Serum	43 days	Liquid Ready to Use	Salicylate Calibrator	43 days	2°-8°C

Fentanyl	EIA	Urine	60 days	Liquid Ready to Use- User Defined. Reagent R1 and Reagent R2 poured into 55 mL wedges.	Calibrator A (negative) and Calibrator B (cutoff)	30 days	2°-8°C
Oxycodone	EIA	Urine	28 days	Liquid Ready to Use- User Defined. Reagent A is R1 and Reagent E is R2 poured into 20 mL wedges.	Neg Cal Reference and Oxycodone Cal 100	7 days	2°-8°C

Bulk Solutions

	Purpose	Onboard Stability	Preparation	Expiration
ICT Reference	ICT Analysis	Expiration date on bottle	Ready to use	
Alkaline Wash	Wash cuvettes	Expiration date on bottle	Ready to use	
Acid Wash	Wash cuvettes	Expiration date on bottle	Ready to use	
0.5% Acid Wash	Wash sample probe	1 days	5 mL Acid Wash 995 mL reagent grade water	Stability listed on Acid Wash Bulk
10% Detergent B	Wash Reagent Probes	14 days	50 mL Detergent B 450 mL reagent grade water	14 days
Water Bath Additive	Daily Maintenance	N/A	Ready to use- do not top off bottle	
Detergent A	Wash Sample Probe	Expiration date on bottle	Ready to use	
Saline	Sample Dilution	Expiration date on bottle	Ready to use	
ICT Cleaning Fluid	Daily Maintenance	N/A	12 mL ICT Cleaning fluid Added to the ICT Lyophilized bottle	14 days at 2° to 8°C

Note: Class A Glassware is not required to prepare Bulk Solutions

Calibrators

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Calibrator	Abbott Name	Preparation	Open Stability (Days)	Storage Temp after opening	Number of Levels	Requires Set Point Change with New LOT	Assays Calibrated
ICT Serum Cal	ICT Low/High	Ready to Use	7	2-8° C	2	N	Cl-C K-C Na-C
ICT Urine Cal	ICTU Low/High	Ready to Use	7	2-8° C	2	N	Cl-CU K-CU Na-CU
Multiconstituent Cal	MCC	Ready to Use	7	2-8° C	2	Y	AlbG CaC CaCU Chol CreaC CreaCU
							Glu GluCU Fe-PI LactA MAG MAGU
							Phos PhosU TP Trig UA Urea
							UreaU
BHBT Cal	BHOB	Ready to Use	Until Exp Date	2-8° C	1	N	BHBT
Bilirubin Cal	Bil	Ready to Use	7	2-8° C	2	Y	BilD BiliT
CO2 Cal	CO2C	Ready to Use	30	2-8° C	2	Y	CO2C
Lipid Multiconstituent Cal	LIPIDMCC	ADD 1mL H2O	7	2-8° C	1	Y	UHDL DLDL
Urine/ CSF Protein Cal	Upro	Ready to Use	Until Exp Date	2-8° C	5	N	Upro
Ammonia Cal (included with Reagent)	Amm	Ready to Use	120	2-8° C	1	N	Amm
Lipase Cal	Lipase	ADD 3mL H2O	28	2-8° C	1	Y	Lip
Specific Protein Cal	SP	Ready to Use	30	2-8° C	5	Y	C3 C4 Hapt IgA
							IgG IgM TRF
Microalbumin Cal	uAlbCal	Ready to Use	6 months	2-8° C	5	N	uAlb
Prealbumin Cal	PreAlb	Ready to Use	30	2-8° C	5	N	Palb
CRP Cal Set *	32CRP	Ready to Use	90	2-8° C	5	N	CRP32 * See below for details on CRP Calibration
CRP Cal Set *	16CRP	Ready to Use	90	2-8° C	5	N	CRP16 * See below for details on CRP Calibration
Cystatin C Calibrator	CysC	Ready to Use	6 months	2-8° C	6	Y	CysC
Quantia Protein Cal	PROT	Ready to Use	Until Exp Date	2-8° C	5	Y	A1AT
Plasma Protein Cal	PPCS3	Ready to Use	30	2-8° C	1	Y	Cerul
Rheumatoid Factor Cal	RF	Ready to Use	90	2-8° C	5	N	RF
Quantia ASO Cal	ASO	ADD 1mL H2O	15	2-8° C	1	N	ASO
Ethanol Cal	EtohM	Ready to Use	Until Exp Date	2-8° C	2	N	ETOH
B2 Microglobulin Cal	B2M	Ready to Use	Until Exp Date	2-8° C	1	Y	B2M
Quantia Lp(a) Cal	Lpa	ADD 1 mL H2O	15	2-8° C	5	Y	Lpa
Internal Water							AlkP ALT Amy AmyU AST CK GGT LD
TDM Multiconstituent Cal	TDMMCC	Ready to Use	60	2-8° C	6	Y	AMIK CARB DIG GENT PHENO PHENY
							THEO VALP VANCO
Acetaminophen Cal	ACET	Ready to Use	Until Exp Date	2-8° C	1	N	ACETA
Salicylate Cal		Ready to Use	Until Exp Date	2-8° C	1	N	SALIC
Tobramycin Cal	TOBRA	Ready to Use	Until Exp Date	2-8° C	6	N	TOBRA
Clin Chem Cal	CCC-5	ADD 3mL H2O***	2 days #	2-8° C	1	Y	LITHI CRENZ #Can be frozen for 14 days
							*** Wait 30 Minutes
DOA Neg	DOAQL1	Ready to Use	Until Exp Date	2-8° C	1	N	Amphet Barb Benzo Cannab Cocaine Methadone
							Opiate PCP
DOA MC 1	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Amphet Benzo
DOA MC 2	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Barb Benzo Cocaine Methadone PCP
DOA MC 3	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Benzo
DOA MC 4	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Benzo
THC 50	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Cannab
Opiate 300	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Opiate
Fentanyl Calibrator A (Negative)	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Fentanyl
Fentanyl Calibrator B (Positive)	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Fentanyl
Neg Cal Ref	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Oxycodone
Oxycodone Urine Calibrator	See below	Ready to Use	Until Exp Date	2-8° C	1	N	Oxycodone

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CRP Details for Calibration

	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6
CRP 16 (hsCRP	2.5 Bright Yellow	5.0 White	10 Light Yellow	20 Green	80 Pink	[illegible] Red
CRP 32 (CRP	5 White	10 Light Yellow	20 Green	40 Blue	[illegible] Red	320 Brown

hsCRP calibrator contains only the 2.5 calibrator with the Bright Yellow Lid. This calibrator is combined with the CRP calibrators to complete the calibrator set. Once in use the calibrators are all combined in the CRP Calibrator Box.

Drugs of Abuse Details

Analyte	Calibrators		Abbott Name Negative	Abbott Name for Cut off Cal
Amphetamines	DOA Neg	DOA Cal #1	DOAQL1	DOAQL 2
Barbituates	DOA Neg	DOA Cal #2	DOAQ 1	DOAQ 2
Benzodiazepine	DOA Neg	DOA Cal #1,2,3,4	DOASQ1	DOASQ2,3,4,5
Cannabinoids	DOA Neg	THC 50	THCQ1	THCQ2
Cocaine	DOA Neg	DOA Cal #2	DOAQ1	DOAQ2
Opiates	DOA Neg	Opiate 300	OPQ1	OPQ2
Methadone	DOA Neg	DOA Cal # 2	DOAQ1	DOAQ2
PCP	DOA Neg	DOA Cal #2	DOAQ1	DOAQ2
Fentanyl	Fentanyl Calibrator A (Negative)	Fentanyl Calibrator B (Positive)	FEN1	FEN2
Oxycodone	Neg Cal	Oxycodone Urine Cal 100	Immunalysis Negative Reference Cal	Immunalysis Oxycodone Urine Calibrator 100

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Reference Ranges

01/11/2022
Attachment D

	Age	Reference Range		Units
ALBUMIN	0 - 6 DAYS	2.5	3.4	g/dL
	7 DAYS - 5 YEARS	3.9	5.0	
	6 - 18 YEARS	4.0	5.3	
	19 - 60 YEARS	3.5	5.1	
	> 60 YEARS	3.5	4.9	
ACE		12	60	U/L
ALT				U/L
Male	0 - < 1 YEAR	5	33	
	1 - 12 YEARS	9	25	
	13 - 18 YEARS	9	24	
	19-Adult	9	47	
Female	0 - < 1 YEAR	5	33	
	1 - 12 YEARS	9	25	
	13 - 18 YEARS	8	22	
	19-Adult	8	37	
ALP				U/L
Male	0 - 14 DAYS	90	273	
	15 DAYS - < 1 YEAR	134	518	
	1 - 9 YEARS	156	369	
	10 - 12 YEARS	141	460	
	13 - 14 YEARS	127	517	
	15 - 16 YEARS	89	365	
	17 - 18 YEARS	59	164	
	> 19 YEARS	33	120	
Female	0 - 14 DAYS	90	273	
	15 DAYS - < 1 YEAR	134	518	
	1 - 9 YEARS	156	369	
	10 - 12 YEARS	141	460	
	13 - 14 YEARS	62	280	
	15 - 16 YEARS	54	128	
	17 - 18 YEARS	48	95	
	19 - 60 YEARS	33	120	
	> 60 YEARS	37	135	
ALPHA-1-ANTITRYPSIN		90	200	mg/dL
AMMONIA		15	50	umol/L
AMYLASE			< 100	U/L
ASO	0-4 YEARS		<100	IU/mL
	5-17 YEARS		<250	
	ADULT		<200	
AST (w/o PSP)			< 35	U/L
BETA-2_MICROGLOBULIN			<2.5	mg/L
BETA-OH BUTYRATE		0.02	0.27	mmol/L
BILIRUBIN, DIRECT	0 - 27 DAYS	0.0	1.0	mg/dL
	28 DAYS - ADULT	0.0	0.4	

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Reference Ranges

BILIRUBIN, TOTAL	0 - 23 HRS	0.3	7.9	mg/dL
	24 - 35 HRS	0.3	10.0	
	36 - 47 HRS	0.3	12.0	
	48 - 59 HRS	0.3	12.0	
	60 - 71 HRS	0.3	15.0	
	72 - 83 HRS	0.3	15.0	
	84 - 144 HRS	0.3	15.0	
	145 HRS - 13 days	0.3	15.0	
	14 - 20 Days	0.3	8.0	
	21 - 27 Days	0.3	6.0	
	28 DAYS - ADULT	0.3	1.2	
C3		82	193	mg/dL
C4		10	43	mg/dL
CALCIUM	0 - < 1 YEAR	8.5	11.0	mg/dL
	1 - 18 YEARS	9.2	10.7	
	19 YEARS - ADULT	8.5	10.5	
CERULOPLASMIN		17	40	mg/dL
CHOLESTEROL				
Child 0-2 years		No ranges		
Child 2-17 Years	Acceptable		<170	mg/dL
	BORDERLINE High	170	199	
	HIGH		>= 200	
Adult	DESIRABLE		< 200	
	BORDERLINE High	200	239	
	HIGH		>= 240	
CK, TOTAL				U/L
Male		40	230	
Female		30	150	
CHLORIDE		98	111	mmol/L
CARBON DIOXIDE	< 1 YEAR	20	28	mmol/L
	1 - 13 YRS	17	28	
	> 13 YRS	20	29	
Creatinine				mg/dL
Male	0 - 14 DAYS	0.32	0.92	
	15 DAYS - < 2 YEARS	0.10	0.36	
	2 - < 5 YEARS	0.20	0.43	
	5-<12 YEARS	0.31	0.61	
	12 - <15 YEARS	0.45	0.81	
	15 - <19 YEARS	0.62	1.08	
	19 - ADULT	0.60	1.30	
Female	0 - 14 DAYS	0.32	0.92	
	15 DAYS - < 2 YEARS	0.10	0.36	
	2 - <5 YEARS	0.20	0.43	
	5 - <12 YEARS	0.31	0.61	
	12 - <15 YEARS	0.45	0.81	
	15 - <19 YEARS	0.49	0.84	
	19 - ADULT	0.50	1.10	

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Reference Ranges

CRP			<8.0	mg/L
Cystatin C	0-18 years	No Reference		
	19 YEARS - ADULT	0.51	1.05	mg/L
ETOH		0	10	mg/dL
GGT				U/L
MALE & FEMALE	0 - 14 DAYS	23	219	
	15 DAYS - < 1 YEAR	8	127	
	1 - 10 YEARS	6	16	
	11 - 18 YEARS	7	21	
Male	ADULT MALE	13	60	
Female	ADULT FEMALE	8	39	
GLUCOSE				mg/dL
	FASTING	60	99	
	RANDOM	60	139	
2hr GTT	Fasting	60	99	mg/dL
	1 Hour	60	199	
	2 Hour	60	139	
2 hr GTT Pregnancy	Fasting	60	91	mg/dL
	1 Hour	60	179	
	2 Hour	60	152	
3 hr GTT Pregnancy	Fasting	60	94	mg/dL
	1 Hour	60	179	
	2 Hour	60	154	
	3 Hour	60	139	
GLUCOSE, CSF		50	80	mg/dL
HS CRP				mg/L
	LOW RISK		< 1.0	
	AVERAGE RISK	1.0	3.0	
	HIGHER RISK	3.1	10.0	
	ASSOC. WITH INFECTION OR INFLAMMATION		> 10.0	
HAPTOGLOBIN		40	250	mg/dL
HDLC				mg/dL
Male	18-Adult		>/=40	
Female	18-Adult		>/= 50	
Children 2-17 years	Low		<40	
	Borderline Low	40	45	
	Acceptable		>45	
IGA	< 1 YEAR	0	30	mg/dL
	1 - 2 YEARS	0	90	
	3 - 5 YEARS	30	150	
	6 - 13 YEARS	50	220	
	14 - 18 YEARS	50	209	
	Adult	70	365	
IGG	0 - 14 DAYS	320	1400	mg/dL
	15 DAYS - 11 MO	110	700	
	1 - 3 YEARS	320	1150	
	4 - 9 YEARS	540	1360	
	10 - 18 YEARS	660	1530	
	ADULT	550	1650	
IGM	0 - 14 DAYS	10	40	mg/dL
	15 DAYS - 12 WEEKS	10	70	
	13 WEEKS - 51 WKS	20	90	
	1 - 18 YEARS	30	150	
	ADULT	30	263	

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Reference Ranges

IRON				ug/dL
Male		65	175	
Female		50	170	
POTASSIUM	0 - 1 DAY	5.0	7.5	mmol/L
	2 DAYS - 3 MONTHS	4.0	6.0	
	4 MONTHS - ADULT	3.5	5.2	
LACTATE		0.5	2.0	mmol/L
LD				U/L
Male	0 - 30 DAYS	125	735	
	31 DAYS - 12 MONTHS	170	450	
	13 MONTHS - 3 YEARS	155	345	
	4 - 6 YEARS	155	345	
	7 - 9 YEARS	145	300	
	10 - 12 YEARS	120	325	
	13 - 15 YEARS	120	290	
	16 - 18 YEARS	105	235	
	19 - ADULT	100	240	
Female	0 - 30 DAYS	145	765	
	31 DAYS - 12 MONTHS	190	420	
	13 MONTHS - 3 YEARS	165	395	
	4 - 6 YEARS	135	345	
	7 - 9 YEARS	140	280	
	10 - 12 YEARS	120	260	
	13 - 15 YEARS	100	275	
	16 - 18 YEARS	105	230	
	19 - ADULT	100	240	
LDL, DIRECT		50	129	mg/dL
LP(a)			< = 30	mg/dL
LIPASE		7	60	U/L
MAGNESIUM		1.7	2.5	mg/dL
SODIUM	0 - 1 DAY	126	166	mmol/L
	2 - 29 DAYS	134	144	
	30 DAYS - 1YR	139	146	
	2 - 12 YRS	138	145	
	13 YRS - ADULT	135	145	
PHOSPHORUS	0 - 14 DAYS	5.6	10.5	mg/dL
	15 DAYS - 1 YEAR	4.8	8.4	
	1 - 4 YEARS	4.3	6.8	
	5 - 12 YEARS	4.1	5.9	
	13 - 15 YEARS	3.2	6.2	
	16 - 18 YEARS	2.9	5.0	
	19 - ADULT	2.3	4.4	
PLACA			225	nmol/m/in/mL
PREALBUMIN		18	44	mg/dL
PROTEIN, TOTAL	0 - 14 DAYS	5.3	8.3	g/dL
	15 DAYS - < 1 YEAR	4.4	7.1	
	1 - 5 YEARS	6.1	7.5	
	6 - 8 YEARS	6.4	7.7	
	9 - 18 YEARS	6.5	8.1	
	19 - 60 YEARS	6.4	8.3	
	> 60 YEARS	6.2	8.1	
RHEUMATOID FACTOR			< 15	IU/mL

Reference Ranges

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TIBC		250	425	
Male				
Female				
TRANSFERRIN		163	382	mg/dL
% TRANSFERRIN SAT		15	50	%
TRIGLYCERIDES				mg/dL
18 years - Adult	Normal		<150	
	Borderline High	150	199	
	High	200	499	
	Very High		>/= 500	
2-9 years	Acceptable		<75	
	Borderline High	75	99	
	High		>/= 100	
10-17 years	Acceptable		<90	
	Borderline High	90	129	
	High		>/= 130	
UREA (BUN)	0- 14 DAYS	3	23	mg/dL
	15 DAYS - < 1 YEAR	3	17	
	1 - 10 YEARS	9	22	
	11 - 18 YEARS	7	21	
	19 - ADULT	7	25	
URIC ACID				mg/dL
Male	0 - 13 YRS	1.5	7.6	
	14 YRS - ADULT	3.5	7.2	
Female	0- ADULT	2.6	6.0	

24 hour URINE

AMYLASE, URINE	2	17	U/Hour
CALCIUM, URINE	100	300	mg/Collection
CALCIUM/CREATININE RATIO	0.02	0.26	
CHLORIDE, URINE	110	250	mmol/collection
CREATININE, URINE	800	2500	mg/collection
GLUCOSE, URINE		< 0.9	g//24 hours
POTASSIUM, URINE	25	125	mmol/collection
MAGNESIUM, URINE	50	200	mg/collection
MICROALBUMIN		<30	mg/24 hours
MICROALBUMIN Excretion Rate		</=20	mcg/min
MICROALBUMIN/Creatinine Ratio		<30	mg/g
SODIUM, URINE	40	220	mmol/collection
PHOSPHORUS, URINE	0.3	1.3	g//24 hours
PROTEIN, URINE		< 150	mg/collection
PROTEIN/CREATININE RATIO	0	0.2	
UREA, URINE	12	20	g//24 hours
URIC ACID, URINE	250	750	mg/Collection

CSF

GLUCOSE (ADULT)	50	80	mg/dL
0 - 9 YEARS			
LACTATE	0.5	2.0	mmol/L
LDH	5	30	U/L
PROTEIN	15	45	g/dL

TDM

Acetaminophen		0	30	mcg/mL
Amikacin Peak				
	Peak	20	30	mcg/mL
	Trough	4	8	

Reference Ranges

Beaumont

Carbamazepine		6	12	mcg/mL
Digoxin		0.8	2	ng/mL
Gentamicin				
	Peak	5	10	mcg/mL
	Trough		>2	mcg/mL
Lithium		0.6	1.2	mmol/L
Phenobarbital		20	40	mcg/mL
Phenytoin				
	0-3 years	6	15	mcg/mL
	>3 years	10	20	mcg/mL
Salicylate		0	25	mg/dL
Theophylline		10	20	mcg/mL
Tobramycin				
	Peak	5	10	mcg/mL
	Trough		<2	mcg/mL
Valproic Acid				
	<15 years	50	150	mcg/mL
	>15 years	50	100	mcg/mL
Vancomycin				
	Peak	30	45	mcg/mL
	Trough	</=20		mcg/mL

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Reportable Range

12/23/2022
Attachment E

		LOW	HIGH	Onboard Dilution	EXTENDED RANGE	Diluent/ Dilution	Max Reportable
ACE	U/L	1	120				>120
ALBUMIN	g/dL	0.4	10.5				>10.5
ALBUMIN, Fluid	g/dL	0.4	10.5				>10.5
ALP	U/L	5	4555				>4555
ALT	U/L	6	4113	X5	20565		>20565
Ammonia	umol/L	8	997	X1.85	1844	Saline/X4	>3688
AMYLASE	U/L	3.0	6554				>6554
AMYLASE, Fluid	U/L	3.0	6554				>6554
AST	U/L	3	4202	X5	21010		>21010
BHBT	mmol/L	0.01	4.5	X10	45		>45
BILIRUBIN, DIRECT	mg/dL	0.1	15.0				>15.0
BILIRUBIN, TOTAL	mg/dL	0.1	25.0	X5/X10	125/250		>250
BILIRUBIN, TOTAL, Fluid	mg/dL	0.1	25.0	X10	250		>250
CALCIUM	mg/dL	2.0	19.0				>19.0
CHOLESTEROL	mg/dL	7	705	X4	2820		>2820
CHOLESTEROL, Fluid	mg/dL	7	705	X4	2820		>2820
CK	U/L	7	4267	X10	42670	Saline	42670**
CHLORIDE	mmol/L	50	150				>150
CO2	mmol/L	5	50	X2	100		>100
CREATININE	mg/dL	0.10	37.00				>37
CREATININE, Fluid	mg/dL	0.10	37.00				>37
CREATININE ENZ	mg/dL	0.10	37.00				>37
ETOH	mg/dL	10	600				>600
GGT	U/L	4	9256				>9256
GLUCOSE	mg/dL	5	800	X5	4000		>4000
GLUCOSE, Fluid	mg/dL	5	800	X5	4000		>4000
HDLC	mg/dL	5	180				>180
IRON	ug/dL	5	1000	X6.55	6550		>6550
POTASSIUM	mmol/L	1.0	10.0				>10.0
Lactate	mmol/L	0.2	13.3	X4	53		>53
Lactate, CSF	mmol/L	0.2	13.3	X4	53		>53
LD	U/L	10	4500				>4500
LD, Fluid	U/L	10	4500				>4500
LDLC - DIRECT	mg/dL	1	800				>800
LIPASE	U/L	4	1200				>1200
Lp(a)	mg/dL	1.3	90	X4			>360
MAGNESIUM	mg/dL	0.6	9.5				>9.5
SODIUM	mmol/L	100	200				>200
PHOSPHORUS	mg/dL	0.7	25.3				>25.3
PLACA	nmol/min/mL	10	382				>382
PROTEIN, TOTAL	g/dL	0.8	18.4				>18.4
PROTEIN, TOTAL, Fluid	g/dL	0.8	18.4				>18.4
TRIGLYCERIDES	mg/dL	7	1420	X4	5680	Saline X10	>7500
TRIGLYCERIDES, Fluid	mg/dL	7	1420	X4	5680	Saline X10	>7500
UREA, BLOOD	mg/dL	2	125	X5	625		>625
UREA, Fluid	mg/dL	2	125	X5	625		>625
URIC ACID	mg/dL	1.0	33.1				>33.1

**Samples above the CK stated maximun dilution are diluted in duplicate with 2 different dilution factors before reporting. (ex. X20 and x40) Dilutions should agree within 10%.

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Reportable Range

12/23/2022
Attachment E

		LOW	HIGH	Onboard Dilution	EXTENDED RANGE	Diluent/ Dilution	Max Reportable
AMYLASE, URINE	U/L	3	2000				>2000
CALCIUM, URINE	mg/dL	2.0	24.0	X5	120		>120
CHLORIDE, URINE	mmol/L	20	300				>300
CREATININE, URINE	mg/dL	5.0	740				>740
GLUCOSE, CSF	mg/dL	1	800				>800
GLUCOSE, URINE	mg/dL	1	500				>500
LD, CSF	U/L	10	2000		4500		>4500
MAGNESIUM, URINE	mg/dL	1.8	26.7	X9	80.1		>80.1
MICROALBUMIN	mg/dL	0.5	50	X4 / X16	200 / 800		>800
SODIUM, URINE	mmol/L	20	400				>400
PHOS, URINE	mg/dL	5	186				>186
POTASSIUM, URINE	mmol/L	1.0	300				>300
UREA, URINE	mg/dL	40	1980				>1980
URIC ACID, URINE	mg/dL	5.0	100				>100
Protein, CSF	mg/dL	7	200	X10	2000		>2000
PROTEIN, URINE	mg/dL	7	200	X2 / X20	400 / 4000	Saline X40	>7000
A1AT	mg/dL	25.0	300.0	X5	1500		>1500
ASO	IU/mL	50	850	X13.88	4247		>4247
B2 Microglobulin	mg/L	0.25	16	X6	96		>96
PREALBUMIN	mg/dL	3	50	X4	200		>200
TRANSFERRIN	mg/dL	19	525	X2	1050		>1050
RF	IU/mL	15	200	X10	2000		>2000
C3	mg/dL	11	340	X2	680		>680
C4	mg/dL	3	60	X2	120		>120
CERULOPLASMIN	mg/dL	2	65				>65
HS CRP	mg/L	0.1	160	X10	1600		>1600
CRP	mg/L	0.2	320	X10	3200		>3200
Cystatin C	mg/L	0.35	8.00				>8.00
HAPTOGLOBIN	mg/dL	8	255	X4	1020		>1020
IGA *	mg/dL	5	3650	X10	7300		>7300
IGG*	mg/dL	109	4150	X4	16000		>16000
IGM*	mg/dL	5	1600	X10	3200	Saline X20	>7000

* Verify dilution condition is undiluted before reporting IGA and IGM as "Less Than"
Verify dilution condition is 3:1 before reporting IGG as "Less Than"

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Reportable Range

12/23/2022
Attachment E

		LOW	HIGH	Onboard Dilution	EXTENDED RANGE	Diluent/ Dilution	Max Reportable
Acetaminophen	ug/mL	3	377		377	Saline	Endpoint
Amikacin	ug/mL	2	50	X4	200	Saline	Endpoint
Carbamazepine	ug/mL	1.9	20	X2	40	Saline	Endpoint
Digoxin	ng/mL	0.2	5.0	X4 or X8	40	Saline	Endpoint
Gentamicin	ug/mL	0.5	10	X2	20	Saline	Endpoint
Lithium	mmol/L	0.10	3.51	X40	7.02	Saline	Endpoint
Methotrexate	umol/L	0.05	1.20	X10 or X100	12.00 or 120.00	Buffer	>12000.00
Phenobarbital	ug/mL	2.0	80	X2	160	Saline	Endpoint
Phenytoin	ug/mL	1.8	40	X4	160	Saline	Endpoint
Salicylate	mg/dL	5.0	100	X5	500	Saline	Endpoint
Theophylline	ug/mL	2.0	40	X4	160	Saline	Endpoint
Tobramycin	ug/mL	0.2	10			Tobra Cal 1	Endpoint
Valproic Acid	ug/mL	13	150	X4 or X8	1200	Saline	Endpoint
Vancomycin	ug/mL	1.1	100	X4	400	Saline	Endpoint

Due to the need to access the potential for toxicity and to assist in monitoring a patient after a toxic ingestion it is necessary to manually dilute until a concentration within the AMR is obtained. Laboratory policy for TDM is to dilute to a concentration unless otherwise indicated.

		Cut off	Dilution
Amphet/Methamphet	ng/mL	500	DO NOT DILUTE
Barbituate	ng/mL	200	DO NOT DILUTE
Benzodiazapine	ng/mL	200	DO NOT DILUTE
Cannabannoid	ng/mL	50	DO NOT DILUTE
Cocaine	ng/mL	300	DO NOT DILUTE
Methadone	ng/mL	300	DO NOT DILUTE
Opiates	ng/mL	300	DO NOT DILUTE
PCP	ng/mL	25	DO NOT DILUTE
Fentanyl	ng/mL	1.0	DO NOT DILUTE
Oxycodone	ng/mL	100	DO NOT DILUTE

DAU Special Handling

If a numeric result is not produced by the instrument and the error code 1350 (unable to calculate result) is obtained, the urine sample should be centrifuged and re-analyzed. If a result is still not obtained add the appropriate comment to the report in the LIS. Use the smartphrase abbreviate .DSCR, to easily access the comment for each test in the LIS.
" _____screen cannot be performed due to interference. Consider confirmatory testing if clinically indicated."

If a urine sample is suspected to be dilute (no color or very pale), a urine creatinine and a specific gravity should be run. If the specific gravity is <1.003 and the urine creatinine concentration is <20 mg/dL , report the results with comment "This specimen has been determined to be dilute".

Dilution Guide			
Dilution	DILUENT	SAMPLE	Program at
X2	100uL	100uL	2
X4	300uL	100uL	4
X5	400uL	100uL	5
X10	900uL	100uL	10
X16	750uL	50uL	16
X20	950uL	50uL	20

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Hemolysis, Icteria, Lipemia Interference

11/17/2022
Attachment F

HEMOLYSIS	Cancel all tests and request a redraw at Hemolysis index 500 and above unless listed below.

ABBOTT	Comment	Hemolysis Value
Ammonia	CANCEL	50
Iron	CANCEL	100
Iron	Variable	50
L.D.H.	INCREASED	50
Potassium	INCREASED	50
Protein, Total	INCREASED	50
D. Bili	DECREASED	50
Lactic Acid	INCREASED	100-199
AST	INCREASED	100
Magnesium	INCREASED	100
Phosphorous	INCREASED	100
Lactic Acid	CANCEL	200
Acetaminophen	CANCEL	200
Amylase	DECREASED	250
CK	INCREASED	250
T Bilirubin	DECREASED	500
Salicylate	CANCEL	600
Phenobarbital	CANCEL	800
Phenytoin	CANCEL	800
Carbamazepine	CANCEL	800
Theophylline	CANCEL	800
Valproic Acid	CANCEL	1000
Tobramycin	CANCEL	1000
Digoxin	CANCEL	1000
Amikacin	CANCEL	1000
Vancomycin	CANCEL	1150
Gentamicin	CANCEL	2000

Fluids	Cancel all fluid tests and request a redraw at Hemolysis index 500 and above unless listed below.

Fluid	Hemolysis Value
Albumin	DO NOT CANCEL
Cholesterol	DO NOT CANCEL
Creatinine	DO NOT CANCEL
Glucose	DO NOT CANCEL
Triglycerides	DO NOT CANCEL
Urea Nitrogen	DO NOT CANCEL
Lactic Acid, CSF	CANCEL AT 200
Amylase	CANCEL AT 800
Bilirubin	CANCEL AT 1000

For established in-vivo hemolysis or NICU (any age) or neonatal (<4 weeks) and sample H index >500, report the following tests with comment as indicated.

ABBOTT Test	Comment
Sodium	
Potassium	INCREASED
Chloride	
CO2	
Glucose	
BUN	
Creatinine	
Calcium	
T. Bilirubin	DECREASED
Magnesium	INCREASED
Phosphorus	INCREASED
Transferrin	
LD	
Haptoglobin	
Albumin	
CRP	
Ferritin	

LIPEMIA **All Samples including Fluids will be airfuged at 200 EXCEPT LIPID Panels**

ABBOTT	Comment	Lipemia Value
Magnesium	DECREASED	50
Ammonia *	RESULT MAY BE COMPROMISED	100-199
Calcium	DECREASED	125
Urea	DECREASED	125

*** Ammonia: Immediately centrifuge to separate plasma from cells. On visual recognition of lipemia or lipemia index > or = 100, remove a plasma aliquot and airfuge (where available). Continue with approved dilutions as necessary to reduce interference (whether or not sample was airfuged). Add comment from table above and comment indicating the sample was airfuged (where appropriate).**

ICTERUS

ABBOTT	Comment	Icterus Value
Iron	RESULT MAY BE COMPROMISED	2.5
Protein, Total	DECREASED	10
Ammonia	Program Auto Dilution 1:1.85 Manually dilute X2 and program with dilution if needed to resolve	20 or absorbance error
Phosphorous	INCREASED	25
Creatinine	DECREASED	30

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Tests by Campus

02/17/2023
Attachment G

Assay	Dearborn	Royal Oak	Grosse Pointe	Troy	Canton	Taylor	Trenton	Wayne	Farmington Hills	Lenox	Livonia
Acetaminophen	X	X	X	X	X	X	X	X	X	X	X
Amphet/Methamphetamine	X	X	X	X	X	X	X	X	X	X	X
Barbiturates	X	X	X	X	X	X	X	X	X	X	X
Benzodiazepines	X	X	X	X	X	X	X	X	X	X	X
B-OH Butyrate	X	X	X	X	X	X	X	X	X	X	X
Cannabinoids	X	X	X	X	X	X	X	X	X	X	X
Cocaine	X	X	X	X	X	X	X	X	X	X	X
Ethanol	X	X	X	X	X	X	X	X	X	X	X
Fentanyl	X	X	X	X	X	X	X	X	X	X	X
Methadone	X	X	X	X	X	X	X	X	X	X	X
Opiates	X	X	X	X	X	X	X	X	X	X	X
Oxycodone	X	X	X	X	X	X	X	X	X	X	X
Phencyclidine (PCP)	X	X	X	X	X	X	X	X	X	X	X
Salicylate	X	X	X	X	X	X	X	X	X	X	X
Albumin BCG	X	X	X	X	X	X	X	X	X	X	X
Alkaline Phosphatase	X	X	X	X	X	X	X	X	X	X	X
ALT	X	X	X	X	X	X	X	X	X	X	X
Ammonia	X	X	X	X		X	X	X	X	X	X
Amylase	X	X	X	X	X	X	X	X	X	X	X
AST	X	X	X	X	X	X	X	X	X	X	X
Calcium	X	X	X	X	X	X	X	X	X	X	X
Cholesterol	X	X	X	X					X		
CK	X	X	X	X	X	X	X	X	X	X	X
CO2	X	X	X	X	X	X	X	X	X	X	X
Creatinine	X	X	X	X	X	X	X	X	X	X	X
Direct Bilirubin	X	X	X	X	X	X	X	X	X	X	X
Direct LDL		X									
GGT	X	X		X					X		
Glucose	X	X	X	X	X	X	X	X	X	X	X
HDL Ultra	X	X	X	X					X		
ICT Module (Cl, NA, K)	X	X	X	X	X	X	X	X	X	X	X
Iron	X	X	X	X					X		
Lactic Acid	X	X	X	X	X	X	X	X	X	X	X
LDH	X	X		X	X	X	X	X	X	X	X
Lipase	X	X	X	X	X	X	X	X	X	X	X
Magnesium	X	X	X	X	X	X	X	X	X	X	X
Phosphorus	X	X	X	X	X	X	X	X	X	X	X
Total Bilirubin	X	X	X	X	X	X	X	X	X	X	X
Total Protein	X	X	X	X	X	X	X	X	X	X	X
Triglyceride	X	X	X	X					X		
Urea Nitrogen	X	X	X	X	X	X	X	X	X	X	X
Uric Acid	X	X	X	X	X	X	X	X	X	X	X
Urine Protein	X	X	X	X				X	X		
CSF Protein	X	X	X	X	X	X	X	X	X	X	X
Alpha-1-Antitrypsin		X									
ASO		X									
Beta2 Microglobulin		X									
Ceruloplasmin		X									
Complement 3	X	X									
Complement 4	X	X									
CRP	X	X	X	X		X			X		
hsCRP	X	X							X		
Cystatin C		X									
Haptoglobin	X	X									
Immunoglobulin A	X	X									
Immunoglobulin G	X	X									
Immunoglobulin M	X	X									
Lp(a)		X									
Microalbumin	X	X	X	X					X		
Prealbumin	X	X	X	X					X		
RF	X	X									
Transferrin	X	X	X	X					X		
Amikacin		X									
Carbamazepine	X	X									
Digoxin	X	X	X	X	X	X	X	X	X	X	X
Gentamicin	X	X									
Lithium	X	X									
Phenobarbital	X	X									
Phenytoin	X	X	X	X					X		
Theophylline	X	X									
Tobramycin	X	X									
Valproic Acid	X	X	X	X		X	X	X	X		
Vancomycin	X	X	X	X		X	X	X	X		

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Specimen Stability

01/11/2022
Attachment H

	Centrifuged SST Tubes			Red Top Tubes without Gel barrier			Plasma		
	RT	2° - 8° C	-20° C pourover	RT	2° - 8° C	-20° C pourover	RT	2° - 8° C	-20° C pourover
Albumin	4 hours	7 days	7 days	4 hours			48 hours	7 days	7 days
Alkaline Phosphatase	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
ALT	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Ammonia (EDTA)								2 hours	14 days
Amylase	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
AST	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
BHBT	4 hours	7 days	7 days	4 hours			4 hours	7 days	7 days
Calcium	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Chloride	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Cholesterol	4 hours	7 days	7 days	4 hours					
CK	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
CO2 (closed tube)	4 hours	72 hours	7 days	4 hours			4 hours	72 hours	7 days
Creatinine	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Direct Bilirubin (light protected)	4 hours	7 days	7 days	4 hours			4 hours	7 days	7 days
Direct LDL	4 hours	7 days	7 days	4 hours					
Ethanol	24 hours	72 hours	7 days	24 hrs	72 hours	7 days	24 hours	72 hours	7 days
GGT	4 hours	7 days	7 days	4 hours					
Glucose (SST or FIOx)	4 hours	7 days	7 days	4 hours			4 hours (PST) 24 hours(FIOx)	72 hours (PST) 7 days(FIOx)	7 days
HDL Ultra	4 hours	7 days	7 days	4 hours					
Iron	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Lactic Acid (FIOx)							8 hours	7 days	30 days
LD	4 hours	48 hours	7 days	4 hours					
Lipase	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Magnesium	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Phosphorus	4 hours	7 days	7 days	4 hours			72 hours	4 days	7 days
PLACA	24 hours	14 days	18 months	4 hours	30 hours				
Potassium	4 hours	7 days	7 days	4 hours			72 hours	5 days	7 days
Potassium, Pl (Li Hep)							2 hours	7 days	
Sodium	4 hours	7 days	7 days	4 hours			72 hours	7 days	7 days
Total Bilirubin	4 hours	7 days	7 days	4 hours			4 hours	7 days	7 days

Total Protein	4 hours	7 days	7 days	4 hours
Triglyceride	4 hours	7 days	7 days	4 hours
Urea Nitrogen	4 hours	7 days	7 days	4 hours
Uric Acid	4 hours	7 days	7 days	4 hours
Alpha-1-Antitrypsin	12 hours	7 days	3 months	12 hours
ASO	8 hours	7 days	3 months	2 hours
Beta2 Microglobulin	2 hours	7 days	14 days	2 hours
Ceruloplasmin	12 hours	7 days	3 months	12 hours
Complement 3	12 hours	7 days	3 months	12 hours
Complement 4	12 hours	7 days	3 months	12 hours
CRP	24 hours	7 days	3 months	12 hours
hsCRP	24 hours	7 days	3 months	12 hours
Cystatin C	14 days	21 days	3 months	7 days
Haptoglobin	4 hours	7 days	7 days	4 hours
Immunoglobulin A	12 hours	7 days	3 months	12 hours
Immunoglobulin G	12 hours	7 days	3 months	12 hours
Immunoglobulin M	12 hours	7 days	3 months	12 hours
Lp(a)	4 hours	3 days	2 months	4 hours
Prealbumin	4 hours	7 days	7 days	4 hours
RF	4 hours	7 days	3 months	4 hours
Transferrin	12 hours	7 days	3 months	12 hours

72 hours	7 days	7 days	
4 hours	7 days	7 days	
72 horus	7 days	7 days	
14 days	21 days	3 months	
12 hours	3 days	6 months	

	Red Top Tubes without Gel barrier			Without Gel Barrier Pourovers		
	RT	2° - 8° C	-20° C	RT	2° - 8° C	-20° C
Acetaminophen	2 hours	24 hours		2 hours	7 days	3 months
Amikacin	2 hours	24 hours		4 hours	7 days	1 month
Carbamazepine	2 hours	24 hours		2 hours	7 days	3 months
Digoxin	2 hours	24 hours		3 hours	8 days	4 months
Gentamicin	2 hours	24 hours		2 hours	7 days	3 months
Lithium	2 hours	8 hours		24 hours	7 days	3 months
Phenobarbital	2 hours	24 hours		2 hours	7 days	3 months
Phenytoin	2 hours	24 hours		2 hours	7 days	3 months
Salicylate	2 hours	24 hours		2 hours	7 days	3 months

Theophylline	2 hours	24 hours	2 hours	7 days	3 months
Tobramycin	2 hours	24 hours	2 hours	7 days	3 months
Valproic Acid	2 hours	24 hours	2 hours	7 days	3 months
Vancomycin	2 hours	24 hours	2 hours	7 days	3 months

	Urine		
	RT	2° - 8° C	-20° C pourover
Amphet/Methamphet	2 hours	24 hours	3 months
Barbiturates	2 hours	24 hours	3 months
Benzodiazepines	2 hours	24 hours	3 months
Cannabinoids	2 hours	24 hours	3 months
Cocaine	2 hours	24 hours	3 months
Methadone	2 hours	24 hours	3 months
Opiates	2 hours	24 hours	3 months
Phencyclidine (PCP)	2 hours	24 hours	3 months
Fentanyl	2 hours	24 hours	3 months
Oxycodone	2 hours	24 hours	3 months
Amylase, URINE	4 hours	4 days	Allowed
Calcium, URINE	4 hours	7 days	Allowed
Chloride, URINE	4 hours	7 days	Allowed
Creatinine, URINE	4 hours	4 days	Allowed
Glucose, URINE	4 hours	4 days	Allowed
Magnesium, URINE	4 hours	7 days	Allowed
Microalbumin	4 hours	7 days	Allowed
Sodium, URINE	4 hours	7 days	Allowed
Phosphorus, URINE	4 hours	7 days	Allowed
Potassium, URINE	4 hours	7 days	Allowed
Urea, URINE	4 hours	4 days	Allowed
Uric Acid, URINE	4 hours	7 days	Allowed
Protein, URINE	4 hours	7 days	Allowed

Beaumont

Fluid Reference Guide

07/13/2022
Attachment I

Approved List of fluids for Abbott Architect Chemistry Analyzers

	CSF	Peritoneal	Pleural	Dialysate	Pancreatic	Fecal	Amniotic	Pericardial
Albumin		X	X					
Amylase		X	X		X			
Total Bilirubin		X	X					
Calcium								
Chloride						X		
Cholesterol		X	X					
Creatinine		X		X				
Glucose		X	X	X	X		X	X
Glucose, CSF	X							
Lactic Acid	X							
LD	X	X	X					X
Magnesium								
Potassium						X		
Protein, CSF	X							
Protein, Total		X	X					X
Sodium						X		
Triglycerides		X	X					
Urea Nitrogen				X				

CSF has been approved by the FDA for Glucose and Protein testing on the analyzer and will be tested using the analyzer designated method. (Glucose, CSF and Protein, CSF). The Peritoneal, Pleural, Dialysate, Pancreatic and Amniotic fluid have been laboratory validated using the Serum Method. Fecal and Breast Milk have been validated using the Urine Method. Refer to **Attachment C** for the reportable ranges.
Note: All Fluids with Chemistry tests requested are centrifuged before testing. HIL rules apply to all fluids.

Reference Ranges

Albumin	
Peritoneal Fluid	Because of the wide range of albumin levels seen in peritoneal fluid, results are best evaluated using the serum-ascites albumin gradient. A serum to fluid gradient >1.1 g/dL is seen in transudates. A serum to fluid gradient </= 1.1 g/dL is seen in exudates.
Pleural Fluid	A serum to fluid gradient </= 1.2 g/dL is consistent with exudate.

Amylase	
Peritoneal Fluid	Values greater than or equal to 3X a simultaneously analyzed serum value are considered abnormal
Pleural Fluid	<104 U/L or a fluid to serum ratio less than 1.5-2.0
Pancreatic Fluid	Pancreatic pseudocysts generally contain significantly elevated amylase (e.g.) >250 IU/L, whereas mucinous and serous cysts and adenocarcinoma usually have lower concentraions. Results should be used in conjunction with clinical information, imaging studies, cytology and other pancreatic cyst markers.

Total Bilirubin

Peritoneal Fluid	Ascitic fluid bilirubin < 6mg/dL and a ascitic flluid to serum bilirubin <1.0 mg/dL appears to be consistent with bile peritonitis.
Pleural Fluid	Fluid to serum ratio >/= 0.6 is consistent with exudate

Cholesterol	
Peritoneal Fluid	<48 mg/dL
Pleural Fluid	Fluid to serum ratio>/= to 0.3 or fluid cholesterol >45 mg/dL = exudate

Creatinine	
Peritoneal Fluid	0.5-2.0 mg/dL

Glucose	
Amniotic Fluid	>15mg/dL
CSF	50-80 mg/dL
Peritoneal Fluid	approximates that found in serum
Pleural Fluid	>60 mg/dL or fluid to serum ratio greater than 0.5
Pericardial Fluid	Not established
Pancreatic Fluid	Low pancreatic cyst fluid glucose (less than 50 mg/dL) is predictive of mucinous versus non-mucinous pancreatic cystic lesions.
Lactic Acid	
CSF	0.5-2.0 mmol/L

LD	
CSF	5- 30 U/L
Peritoneal Fluid	<63 U/L
Pleural Fluid	Pleural fluid to serum ratio of greater than or equal to 0.6 or pleural fluid LD greater than or equal to 2/3rds the upper limit of normal serum LD level is consistent with exudate. Pleural fluid to serum ratio of less than 0.60 or pleural fluid LD less than or equal to 2/3rds the upper limit of normal serum LD level is consistent with transudate.
Pericardial Fluid	Not established

Protein	
CSF	15-45 mg/dL
Peritoneal Fluid	Transudate <3.0 g/dL, Exudate>/=3.0 g/dL
Pleural Fluid	Transudate <3.0 g/dL, Exudate>/=3.0 g/dL
Pericardial Fluid	Not established

Triglycerides	
Peritoneal	<65 mg/dL
Pleural Fluid	>/= 110 mg/dl indicative for chylous effusion, <50 mg/dL indicative of non-chylous effusion, 50-109 mg/dL are equivocal