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Abbott Architect Immunoassay System Analyzer Operation

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To describe how to operate the Abbott Architect Immunoassay System Analyzer

II. PRINCIPLE:

The ARCHITECT immunoassays utilize a two-step process to determine the presence of these analytes in human serum (or plasma) using CMIA (chemiluminescent microparticle immunoassay) technology with flexible assay protocols, referred to as Chemflex.

A. Sample and anti-analyte (or in the case of antibody testing – antigen) coated paramagnetic microparticles are combined. The analyte present in the sample binds to the anti-analyte/ antigen coated microparticles.

B. A magnet attracts the paramagnetic microparticles (bound to specific analyte) to the wall of the reaction vessel.

C. The wash zone manifold washes the reaction mixture to remove unbound materials.

D. After washing, anti-analyte/antigen acridinium-labeled conjugate is added to create a reaction mixture.

E. Following another wash cycle, Pre-Trigger (hydrogen peroxide) and Trigger (sodium hydroxide) solutions are added to the reaction mixture.

F. The resulting chemiluminescent reaction is measured as relative light units (RLUs).

G. The ARCHITECT iSystem optics obtains the RLU readings, and then converts them to assay-specific analyte concentration units or qualitative interpretations for index (cutoff) assays.

III. CLINICAL SIGNIFICANCE:

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

IV. OBJECTIVE:

The ARCHITECT *i* 2000SR and *i* 1000SR systems are fully automated immunoassay systems allowing random and continuous access sample processing as well as priority processing. The ARCHITECT *i* 2000SR processes up to 200 CMIA tests per hour, using up to 25 onboard reagent kits (100 and/or 500 tests) in a temperature-controlled reagent carousel and provides STAT processing. The ARCHITECT *i* 1000SR processes up to 100 CMIA tests per hour, using up to 25 onboard reagent kits (100 tests) in a temperature controlled reagent carousel and provides STAT processing.
Please note that the complete Operations Manual for the ARCHITECT *i* 2000SR and *i* 1000SR can be accessed directly from the instrument screen. The operator may do so by:

A. Selecting Overview icon
B. Selecting Operations Manual

V. SPECIMEN COLLECTION AND HANDLING:

A. **Collection Requirements**
    1. Follow all usual 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.

B. **Specimen Preparation and Storage**
    1. Ensure that serum specimens collected in tubes containing a gel separator have at least 8mm of serum above the gel to avoid contamination of the specimen during pipetting.
    2. Inspect all samples for bubbles. Remove bubbles with a clean applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
    3. Ensure complete clot formation in serum specimens has taken place prior to centrifugation (if applicable). 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.

C. **Sample Volume:**
Required sample volume can be obtained by printing the Order List Report after order is placed. The stated volume includes the 50µL dead space using an Abbott short sample cup.

D. **Specimen Handling**
    1. For optimal results, serum and plasma specimens should be free of fibrin, red blood

cells, or other particulate matter. Centrifuge specimens containing fibrin, red blood cells, or particulate matter prior to use to ensure consistency.

2. If proper specimen collection and preparation cannot be verified, or if samples have been disrupted due to transportation or sample handling, an additional centrifugation step is recommended. Centrifugation conditions should be sufficient to remove particulate matter. Aliquots poured versus pipetted from specimen tube types that do not include serum separators are at higher risk of including particulates and generating erroneous results.
3. To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.
4. Prepare frozen specimens as follows. Frozen specimens must be completely thawed before mixing.
5. Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous. If samples are not mixed thoroughly, inconsistent results may be obtained.

E. **Specimen Stability**
See **Attachment H** for a detailed list of specimen stability guidelines.

VI. REAGENTS:

A. **Reagent Handling**

1. Do not use reagent kits beyond the expiration date.
2. **Do not pool reagents within a kit or between kits.**
3. Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment.
Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in the package inserts.
4. To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
5. Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
6. Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
7. Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations

Manual, Section 5.

B. **Indications of Reagent Deterioration**

C. When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

D. Note: Refer to **Attachment B** for a detailed list of reagent preparation and storage requirements.

VII. EQUIPMENT COMPONENTS:

The ARCHITECT consists of three primary components.

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. The complete Operations Manual can be accessed from the instrument screen. The Operator selects Overview icon and then Operations Manual.

VIII. SUPPLIES:

A. **Reagent Cartridges: Reagent cartridges are containers used in the reagent supply centers to hold the reagents used during operation.**

B. **Calibrators: Calibrators are samples that contain known concentrations of an analyte.**

C. **Reaction Vessels**

D. **Sample Cups**

E. **Bulk Solutions**

1. Trigger Solution
2. Pre-trigger Solution
3. Concentrated Wash Buffer

F. **Diluents**

1. Multi-Assay Manual Diluent
2. HBsAG Qualitative Confirmatory Manual Diluent

G. **Aliquot tubes: Sarstedt SC TUBE 6.5 mL 13x90 (60.503.010)**

H. **False bottom Aliquot tubes:** Sarstedt FB Tube 2.5 mL (60.614.065)

IX. MAINTENANCE:

Maintenance is performed Daily, Weekly, 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, 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 by selecting the "Close Window" button.

X. CALIBRATION:

A. **Calibration is required when:**

1. A new reagent lot number is used
2. A new assay file that requires a calibration is installed
3. Documentation accompanying a new version of an existing assay file states calibration is required
4. The calibration curve has expired
5. At least every six months

B. **Bar coded calibrator samples are automatically processed in the following conditions:**

1. Onboard reagent lots do not have an Active calibration curve.
2. A calibration is not in progress.
3. The expired calibration has not been overridden

C. **Calibration Procedure**

1. The ARCHITECT will test calibrators in duplicate. The calibrators should be priority loaded.
2. A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
3. Once an ARCHITECT calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
    a. A reagent kit with a new lot number is used or

b. Controls are out of range.
For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

D. **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 quality control (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. After calibrators are processed, the system verifies the results by comparing them to the assay-specific calibration parameter specifications. If the results of a calibration fall within the specified range for that assay, the new calibration curve replaces any previous calibration curve and the previous calibration curve status changes to inactive. If the results of a calibration do not fall within the specified range, then the new calibration curve is assigned a status of failed; if there is an existing calibration curve for that assay, it is not replaced.

E. **Curve storage**

1. The ARCHITECT system stores active, inactive and failed calibration curves.
2. The active calibration is stored as the active curve for that reagent lot.
3. A new calibration replaces the previous calibration curve, which then becomes inactive.
4. The new calibration will automatically default to the active curve for the onboard reagent lot.
5. The instrument will store one active curve for up to FOUR different reagent lot numbers of each assay.
    a. A new calibration will replace the oldest active curve if a fifth reagent lot calibrates successfully.
    NOTE: A calibration with a status of Pending QC is considered an active curve but, cannot be used to process tests until at least one level of control completes.
6. A calibration may be manually failed by selecting the Fail Curve button on the Calibration curve window.
Note: Refer to **Attachment C** for a detailed list of calibrators.

XI. QUALITY CONTROL:

At least two levels of quality control material are used daily and assigned to specific work shifts. After a calibration, all three levels of controls must be run. Results should not be reported when QC limits are exceeded unless approved by supervisory staff.

A. **Quality Control with Barcode**

1. Load barcoded QC sample onto the analyzer.
2. All tests associated with that barcode will run without being manually ordered on the instrument.
3. To run one specific analyte by barcode, it will need to be manually ordered.
    a. From the Control order screen select Multi-constituent.
    b. Select the Control List button and then select the desired control
    c. If the desired lot number does not display in the lot box, select the Lot list button and select the desired lot.
    d. Select the desired Level options.
    e. Select the desired Panels and/or Assays.
    f. Select F5 Assay options to specify assay options. Use previous/ next buttons to display each assay if more than one selected.
    g. Select Done to save changes.
    h. Select F2- Add Order.

XII. SPECIAL SAFETY PRECAUTIONS:

Universal precautions are indicated when handling patient specimens and quality control materials. Spills and accidents should be addressed immediately.

XIII. PROCEDURE:

A. **Loading Reagent Cartridges: (*i* 2000SR)**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Invert the reagent cartridge gently to insure homogeneity (30 times).
3. Remove the cartridge cap and place a septum on each cartridge.
4. Remove air bubbles. (An applicator stick can be used for this purpose).
5. Ensure the analyzer is in the Ready state, with the lid indicator light illuminated and open the analyzer lid.
6. Open the reagent access cover.
7. Press the carousel advance button to advance the reagent supply center carousel.
8. Place the reagent cartridge in an open position.

9. Close the reagent access cover.
10. Close the lid of the analyzer.
11. Select F5 – Scan on the Reagent status screen to update the reagent inventory.

B. **Loading Reagent Cartridges: (*i* 1000SR)**

1. Verify the expiration date of the reagent. Do not use expired reagents.
2. Invert the reagent cartridge gently to insure homogeneity (30 times).
3. Remove the cartridge cap and place a septum on each cartridge.
4. Remove air bubbles. (An applicator stick can be used for this purpose).
5. Install the cartridges onto one of the reagent carriers.
6. Ensure the analyzer and Rack Sample Handler (RSH) are in the Running state.
7. Load the carrier into any of the Immunoassay side loading bays.
8. Reagent inventory will automatically update on the system.
   CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

C. **Loading Bulk Solutions (*i*2000SR and *i*1000SR)**

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. From the Snapshot screen select **F-7 Pause** to change status from running to ready.
4. Adjust levels if necessary by selecting **F3-Adjust level**.
5. Update supplies when replacing by selecting **F2- Update supplies. DO NOT** combine partial bottles of bulk solution.
6. Scan barcodes to update Lot Numbers and Expiration dates.
7. Select Done.
8. The supply status screen displays the updated level. The system automatically flushes the replaced solution before testing is performed.

D. **Calibration Procedure: Creating an Assay Calibration Order**

1. From the ARCHITECT SCC (System Control Center), select **Orders** from the menu bar.
2. Select **Calibration order**.
3. Select the desired assay(s) from the Assays list.
4. Select F5 - Assay options to specify calibration options (optional).
   a. Enter a calibrator lot number in the Lot data entry box.
   b. Enter the calibrator expiration date in the Expiration date data entry box.

c. Use the previous/next buttons to display each assay, if more than one assay was selected.

d. Enter the data then repeat for each assay.

5. Select **Done** to save the changes and return to the Calibration order screen.
6. Select **F2 - Add order** to add the calibration order.

E. **Running Samples**

1. **Front Loading without Automation**

a. Place Samples in specimen racks.

b. 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.

c. Place carrier on the Rack Sample Handler (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.

d. Carriers with solid green lights are waiting to be tested. Carriers with blinking green lights have been sampled. Alternating Green and Amber blinking are sampled but there is a problem that will need to be addressed by the operator.

e. Check the status of the samples before unloading by going to Overview, Sample Status screen. Handle any exceptions as needed.

2. **Front Loading with Automation**

a. Place the appropriate module offline on the Integrated User Interface (IUI).

b. The spur should be online. If the spur is not online, press the green button on the spur keypad to initialize. When the green light next to each queue is illuminated, a sample tube can be placed in the carrier at the appropriate gate for sample processing.

c. If the yellow light is illuminated and blinking, sample carriers are scheduled to move and a sample tube should not be placed in the carrier at this time. A blinking yellow light could also indicate an error has occurred. If the yellow light is illuminated and solid, a sample should not be placed in a carrier at this time. The spur could be in stopped or initializing. If both lights are off, the spur is powered off.

d. The ARCHITECT *i* spur has three tube carrier queues for sample tubes that need to be front loaded. The Priority Input Queue contains 6 sample carriers and Routine Input Queue contains 11 sample carriers. The Output Queue contains 4 sample carriers. The spur should always contain 21 sample carriers total.

e. Samples can be placed in the first carrier of each input queue and processing will start when the tube detect sensor detects a tube.

f. Once the sample has been aspirated, it will wait in the Output Queue until the tube is removed from the carrier.

g. Calibrators must be ordered, have a barcode and be loaded in the correct order before running.

h. QC does not need to be ordered but must have a barcode.

i. All patient samples must have a barcode.
Note: Everything that is loaded on the ARCHITECT *i* system using an automation line must be spun, uncapped and have a barcoded label. The power switch is used to turn the power to the ARCHITECT *i* spur on or off. Never turn the power switch to OFF unless directed to do so by an Abbott Representative.

F. **Shutdown/Start Up to the System Control Center (SCC)**

1. Select F3 – Shutdown on the Snapshot Screen.
2. Select OK to confirm shutdown.
3. Wait for the information window to display, then simultaneously press CTRL+ALT+DELETE, confirm Exit.
4. If the dialog window displays "Shutdown Computer", select OK. IF the red Power Off button displays, select the button
5. Locate the central processing unit (CPU). Press and hold the power switch to power off the SCC.
6. Turn off the power to the processing module by moving the power switch down.
7. Press the power switch on the front of the CPU to turn on the SCC.
8. Wait for the Log On window to display. Log on before turning the instrument back on.
9. Ensure the processing module has been powered off for five minutes, then move the power switch up to turn power back on.

G. **Emergency Shutdown**

1. 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.
2. The analyzer may also be powered down by moving the power switch located on the lower left rear of the analyzer down.

XIV. CALCULATIONS AND INTERPRETATIONS:

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. 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 for the dilution factor to be applied.
Samples that generate an error code are held at the instrument as exceptions. The error code is reviewed using the online Operations Manual. When an error code indicates the result is low, the sample is repeated to verify and reported as "less than". When an error code indicates that the result is high, the sample is diluted to rule out interferences. The result reported will follow the Reportable Range guideline for each assay.

XV. REFERENCE RANGES:

Refer to **Attachment D** for a list of reference ranges.

XVI. REPORTABLE RANGE:

Refer to **Attachment E** for a list of reportable ranges.

XVII. LIMITATIONS:

A. Assay results MUST be used with other clinical data, including, but not limited to: patient symptoms, other test results, patient history, clinical impressions, information available from clinical evaluation, and other diagnostic procedures. All data MUST be considered for patient care management.

B. 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.

XVIII. INTERFERING SUBSTANCES:

Consult the Package Inserts accompanying each test for specific information on interferences with endogenous substances and drugs.
Refer to **Attachment F** for interference due to hemolysis, lipemia and icterus.

XIX. WARNINGS:

A. CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

B. The following warnings and precautions apply:

   1. Contains sodium azide. EUH032 Contact with acids liberates very toxic gas.
   2. This material and its container must be disposed of in a safe way.
      NOTE: Refer to Section 8 of the ARCHITECT System Operations Manual for proper handling and disposal of reagents containing sodium azide.

XX. 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

Attachments

Attachment A - Abbott Architect IA Clinical Significance

Attachment B - Abbott Architect IA Reagent Reference Guide

Attachment C - Abbott Architect IA Calibrator Guide

Attachment D - Abbott Architect IA Reference Ranges

Attachment E - Abbott Architect IA Reportable Ranges

Attachment F - Abbott Architect IA HIL

Attachment G - Abbott Architect IA Tests by Campus

Attachment H - Abbott Architect IA Specimen Stability

Attachment I - Abbott Architect IA Infectious Disease Reporting Guide

Attachment J - Abbott Architect IA Fluid Reference Guide

Approval Signatures

Step Description	Approver	Date
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Applicability

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

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Assay	Clinical Significance
AFP Tumor Marker	Alpha-fetoprotein (AFP) is of importance in diagnosing heptocellular carcinoma and is used as a tumor marker in nonseminomatous testicular carcinomas. Alpha-fetoprotein (AFP) is not recommended as a screening test to detect the presence of cancer in the general population. Pregnancy causes elevation of AFP.
BhCG	**In females**, this assay is used to diagnosis pregnancy, investigate suspected ectopic pregnancy, and monitor *in vitro* fertilization patients. Diagnosis of pregnancy can be confirmed as early as day 21 of the menstrual cycle or approximately 1 week after conception. A negative value does not rule out pregnancy. A patient with a negative result (less than or equal to 5 mIU/mL) should be redrawn in 2 days and assayed again because hCG values in normal pregnancy double every 48 hours in the first trimester. Beta HCG doubling times are longer than 2 days for ectopic and shorter for molar pregnancies. In vitro fertilization patients are monitored for beta HCG levels 12 days after embryo transfer. This assay aids in the diagnosis of testicular, ovarian, and uterine gestational trophoblastic tumors and germ cell tumors. Serial results can be used to follow tumor response to ablative surgical therapy or chemotherapy.
CA 19-9	CA 19-9 is useful in monitoring pancreatic, hepatobiliary, gastric, hepatocellular, and colorectal cancer. It may be used for differentiating patients with cholangiocarcinoma and primary sclerosing cholangitis (PSC) from those with PSC alone.
CA 15-3	CA 15-3 is detectable in serum and is widely used as a tumor marker for breast cancer. CA 15-3 has good specificity for both localized and metastatic breast cancer but does not exhibit good sensitivity for localized disease. Elevated CA 15-3 levels are found in the serum of about 60% of preoperative breast cancer patients and in 80% of patients with advanced metastatic breast cancer. CA 15-3 has been used as an indicator of distant metastases (M+ disease) in breast carcinoma and it measures the milk mucin secreted by the tumor. CA 15-3 is insufficiently sensitive in detecting primary or local disease and should not be used for routine screening, diagnosis of localized breast cancer, and follow-up of localized cancers. CA 15-3 is usually not elevated in patients with early stage breast cancer. Elevated levels are found in only 20% of patients with stage I and II disease. Three possible uses of CA 15-3 are: as an adjunct to bone scan, to provide confirmatory results as a screen for metastatic breast cancer, and to monitor patients in follow-up. A rise in CA 15-3 to abnormal levels is highly suggestive of the development of distant metastases. Elevated CA 15-3 levels have been associated with an increase relapse rate in patients who have gone into remission after initial therapy (lead time to relapse, 6.3 months) (1).
CA 125	Conditions that cause elevated CA 125 levels include: ovarian cancer, pregnancy, ovarian cysts, uterine leiomyomas, pelvic inflammatory disease, endometriosis and menstruation. CA 125 is the most important tumor marker for the management of ovarian cancer. It is best used as an adjunct test with ultrasound or in combination with a second tumor marker test. Predictive values approach 100%, when it is added to other diagnostic tests in postmenopausal women. However, because of its lack of specificity, CA 125 is NOT recommended as a general screen for ovarian cancer. Serial CA 125 measurements after surgical debulking and chemotherapy are useful as a prognostic indicator, and the rate of fall of CA 125 levels has a positive correlation with five year survival. Rising CA 125 level post-treatment can often occur before radiological evidence of recurrent disease by as much as 12 months (1).
CEA	Carcinoembryonic antigen (CEA) is a tumor associated antigen. The CEA assay is used as a marker for colorectal, lung, breast, pancreatic carcinoma, and as an adjunct test in the diagnosis of malignant pleural effusions. CEA assay should not be used as a screening test. The CEA assay is a useful tool as a marker for recurrent disease and as a test of the effectiveness of treatment. The CEA assay is used to monitor response to therapy of patients following surgery and/or chemotherapy. A persistent elevation in circulating CEA following treatment is strongly indicative of occult metastatic and/or residual disease and a poor therapeutic response. Decreasing CEA values are generally indicative of a favorable prognosis and a good response to treatment. It is important to obtain a preoperative CEA level for prognosis and to assess the success of surgical resection in patients with colorectal and bronchogenic carcinoma. Patients with normal preoperative CEA values tend to have low recurrence rates and longer median survival times. The higher the preoperative CEA level, the shorter the postoperative disease-free period. CEA serum levels may be elevated 2-18 months prior to clinical detection of colorectal disease recurrence.
C Peptide	C-Peptide levels may aid in distinguishing type 1 and type 2 diabetes. C-Peptide is also useful in the determination of endogenous insulin secretion and the diagnosis of insulinoma. In insulinoma, C-Peptide levels should parallel those of insulin. Factitious hyperinsulinism (i.e., exogenous insulin administration) will have high insulin but low C-Peptide levels.

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Cortisol	Cortisol is the main glucocorticoid (representing 75-90% of the plasma corticosteroids). It plays a central role in glucose metabolism, in the body's response to stress, and in protein catabolism. Cortisol is **elevated** in Cushing's disease (pituitary adenoma producing ACTH), in cortisol-secreting adenomas and carcinomas of the adrenal gland and in ectopic ACTH-secreting tumors. Cortisol levels are **decreased** in primary adrenal insufficiency (increased ACTH), secondary adrenal insufficiency (decreased ACTH) and in congenital adrenal hyperplasia. **This test is not useful for following dosage of exogenous, synthetic corticosteroids.**
DHEA-S	Measurement of dehydroepiandrosterone sulfate (DHEA-SO4, DHEAS), an adrenal steroid, is important in the investigation of abnormal hair growth (hirsutism) and balding (alopecia) in women. It is also of value in the assessment of adrenarche and delayed puberty.
Estradiol	Measurement of estradiol (E2) is used clinically in the investigation and management of fertility disorders, gynecomastia, estrogen-producing ovarian and testicular tumors and in hyperplasia of the adrenal cortex. Serum E_2 is measured to determine the estrogen status of women, such as in some cases of amenorrhea, and as a guide to monitoring follicular development during ovulation induction and to avoid hyper-stimulation.
Ferritin	Serum ferritin concentration, when analyzed with other factors such as serum iron, iron-binding capacity, and tissue iron stores, is valuable in the diagnosis of iron-deficiency anemia, anemia of chronic disease, and conditions such as thalassemia major and hemochromatosis that are associated with iron overload. Measurement of serum ferritin is particularly valuable in distinguishing iron-deficiency anemia caused by low iron stores from those resulting from inadequate iron utilization.
Folate	Both folate and vitamin B_{12} deficiency can cause macrocytic anemia. Appropriate treatment depends on the differential diagnosis of the deficiency. Folate deficiency is usually due to: malnutrition, malabsorption due to disease of the proximal small bowel, increased requirement as in pregnancy and chronic hemolytic states, or acute illness. Folate deficiency may result in depression or macrocytic anemias.
Free T3	Clinically, the FT3 measurement is a second or third level test of thyroid function. It is useful for evaluating the biochemical status of clinically euthyroid patients who have an altered distribution of binding proteins, such as pregnant patients and patients with dysalbuminemia. It also provides a further confirmatory test for hyperthyroidism to supplement the FT4 and sensitive thyrotropin assays. Some investigators recommend the FT3 assay for monitoring thyroid replacement therapy, although it's clinical role is not precisely defined.
Free T4	Free T_4 levels give a more accurate picture of the thyroid status in patients with abnormal T_4-binding globulin levels such as those who are pregnant or those who are receiving treatment with estrogens, androgens, dilantin, or salicylates.
FSH	FSH levels are used as an adjunct in the evaluation of menstrual irregularities, in the workup of patients with suspected hypogonadism, in the prediction of ovulation, in the evaluation of infertility and in the diagnosis of pituitary disorders.
High Sensitivity Troponin I	High sensitivity troponin assays are now the standard of care for biomarker detection of myocardial injury. The major advantages of the this assay are earlier rule-out of acute myocardial injury when TnI is undetectable (< 4 ng/L) and more accurate evaluation of myocardial injury in females due to sex-specific troponin reference intervals.TnI is elevated (above the 99th percentile of an apparently healthy reference population) in cases of severe myocardial injury such as MI, but may also be elevated in the absence of evidence of myocardial ischemia. For example, TnI elevations may be observed in heart failure, renal failure, chronic renal disease, myocarditis, arrhythmias, pulmonary embolism, stress cardiomyopathy, or other clinical conditions. When ordered as a panel, baseline and 2-h troponins will be collected and the difference (D, "delta" value) will be calculated and flagged in the EMR if significant. A single troponin order for the high sensitivity Troponin assay will be available as needed. Please see attached algorithm to guide Troponin evaluation.
Homocysteine	Elevated homocysteine levels are found in patients with recessively inherited metabolic defects such as cystathionine ß-synthase deficiency and decreased methyl tetrahydrofolate reductase activity. Individuals with cystathionine ß-synthase deficiency may have serum homocysteine levels up to 200 micromoles/L. Homocysteine levels may be elevated in vitamin B6, B12, and folate deficiencies. Homocysteine has been shown to be an independent risk factor for atherosclerotic vascular disease. Homocysteine levels greater than the 90th percentile of normal are associated with increased risk for acute myocardial infarction. The risk for coronary vascular disease increases progressively with homocysteine concentration. There is a 13-fold increase in risk associated with a level of 19 micromoles/L as compared to a 9 micromoles/L homocysteine concentration.

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Insulin	The Insulin assay is used for the quantitative measurement of insulin in serum. This test is used as aid in the diagnosis of insulin-producing neoplasms (islet cell tumor, insulinoma), pancreatic islet cell hyperplasia, to evaluate hypoglycemia, and to evaluate insulin production in diabetes mellitus. Insulinoma is a rare, islet-cell tumor with insulin hypersecretion. Ninety percent of these tumors are benign. Patients with insulinoma present with hypoglycemia that is the result of the inappropriate secretion of insulin by the tumor. Plasma insulin concentrations decrease progressively in normal fasting patients. Patients with an insulinoma present with high insulin levels and hypoglycemia. Plasma insulin-to-glucose ratios may also be useful to diagnose insulinoma (1).
LH	LH levels are used as an adjunct in the evaluation of menstrual irregularities, in the workup of patients with suspected hypogonadism, in ovulation timing, in the evaluation of infertility, and in the diagnosis of pituitary disorders.
Myoglobin	Serum myoglobin is used in the assessment of skeletal or myocardial muscle injury. Increases in serum myoglobin are usually detected earlier than increases in CK, CK-MB, or troponin in patients with acute myocardial infarction. This assay is also used to diagnose rhabdomyolysis. Myoglobin levels increase with muscle trauma or ischemia, malignant hyperthermia, exertion, dermatomyositis, polymyositis, and muscular dystrophies.
Progesterone	The determination of progesterone is utilized in fertility diagnosis for the detection of ovulation, assessment of the luteal phase, and to monitor progesterone replacement therapy. After ovulation, there is dramatic rise in progesterone levels (1-21 ng/mL) that persists for about two weeks. If pregnancy occurs, corpus luteum survival is prolonged until progesterone is secreted by the placenta. In in-vitro fertilization (IVF) patients progesterone levels are maintained at concentrations (greater than 40 ng/mL) with additional progesterone replacement. Decreased levels of progesterone are seen in the short and inadequate luteal phase, and in the first trimester of abnormal pregnancies. Progesterone is secreted by the adrenal gland in adult males and in children. In addition, high levels of progesterone can indicate tumors of the adrenals or ovaries.
Prolactin	Prolactin levels aid in the diagnosis of pituitary tumors, amenorrhea, galactorrhea, infertility, and hypogonadism. Prolactin levels aid in monitoring therapy of prolactin-producing tumors. Prolactin values greater than 200 ng/mL usually indicatea prolactinoma. Most other causes of hyperprolactinemia are associated with a level less than 200 ng/mL.
PSA, Free	The % fPSA is used to determine the risk of prostate cancer. Recent studies have suggested that fPSA testing may improve the sensitivity of the PSA test for prostate cancer detection and can minimize unnecessary prostate biopsies in patients with tPSA values between 2.5 and 10 ng/mL. The ultimate decision to perform prostate biopsy should be made by the clinician, based on all relevant clinical and laboratory findings. Elevated levels of Prostate Specific Antigen (PSA) have been associated with benign and malignant prostatic disorders. Studies indicate that in men 50 years or older measurement of PSA is a useful addition to the digital rectal exam in the early detection of prostate cancer. In addition, PSA decreases to undetectable levels following complete resection of the tumor and may rise again with recurrent disease or persist with residual disease. Thus, PSA levels may be of assistance in the management of prostate cancer patients.
PSA, Total	PSA is a serine protease (Kalikrein family) produced by epithelial cells of the acini and ducts of prostate gland. Normally, very little PSA is secreted into the blood. Increased PSA levels may be due to increases in glandular size and tissue damage caused by benign prostatic hypertrophy, prostatitits, and/or prostate cancer. The tPSA assay is used to monitor patients with a history of prostate cancer, both as an indicator of tumor recurrence and response to therapy. The American Cancer Society recommends annual examination with digital rectal examination (DRE) and serum tPSA beginning at age 50 for men with a life expectancy of at least 10 years after detection. For men in a high risk group (African Americans) or those with strong familial predisposition, testing may begin at a younger age.
Testosterone, Total	Serum testosterone assays aid in the evaluation of males with erectile dysfunction, gynecomastia, osteoporosis, infertility, delayed or precocious puberty, and for monitoring replacement therapy. Testing for women and children should be perfomed using the LC-MS/MS procedure.
Troponin I	Increases in troponin I occur in acute coronary syndromes with myocardial necrosis as well as myocardial infarction with ST elevation. Troponin I is detectable about 3-4 hours after the occurrence of cardiac symptoms. Following acute myocardial ischemia, troponin I remains in the serum for several days and can help to detect myocardial events that have occurred up to 7-10 days earlier. Increases are also associated with direct myocardial damage (e.g., myocarditis, pericarditis, contusion, cardioversion), myocardial strain (e.g., CHF, pulmonary hypertension, pulmonary embolus) and demand ischemia (e.g., sepsis, hypotension, atrial fibrillation). Troponin may also be elevated in entities such as renal failure, intracranial hemorrhage and amyloidosis. The mechanism for the latter elevations is unclear. An elevated troponin level is a predictor for poor outcome regardless of its cause.

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TSH	TSH levels aid in evaluating thyroid function and replacement therapy. They are especially useful in the differential diagnosis of primary (thyroid), secondary (pituitary) and tertiary (hypothalamus) hypothyroidism. In primary hypothyroidism, TSH levels are significantly elevated, while in secondary and tertiary hypothyroidism, TSH levels are low or normal. When testing patients on thyroid hormone replacement, blood should be obtained shortly before the patient's next dose. Testing shortly after thyroid hormone intake should not affect TSH results, however it may result in an apparently elevated free T4. If a patient's dose of thyroid hormone is changed, it is recommended that 6-8 weeks be allowed to elapse before retesting.
Vitamin B12	Vitamin B_{12} deficiency is usually due to malabsorption resulting from: deficiency of intrinsic factor, disease or resection of the terminal small bowel, or utilization of the vitamin by excessive bacterial flora in the gut. It may also occur in strict vegetarians where insufficient Vitamin B_{12} is present in the diet. Vitamin B12 deficiency can result in: macrocytic anemia, neuropathy, psychiatric changes, mental impairment (dementia), and infertility. Since macrocytic anemia often requires measurement of both Vitamin B12 and folate levels it may be more economical and convenient to perform both tests at the same time.
BNP	Recommendations for use are: When CHF is suspected, but the diagnosis is not clear cut. Consider re-ordering BNP 1-2 days prior to hospital discharge, looking for a decrease of greater than 50% of admission level or an absolute level of less than 500 pg/mL. Patients with this type of decline are much less likely to be re-admitted because of CHF in the next few weeks. Frequent or daily monitoring of BNP is not appropriate and is strongly discouraged.
PCT	Procalcitonin (PCT) has been shown to help decrease inappropriate antibiotic use and thereby decrease the rate of rise of antibiotic resistance. **It should only be ordered in patients if it will change antibiotic management.** It has been studied in a number of disease states, but the best evidence for use is as an aid in deciding whether to start antibiotics in patients with potential lower respiratory tract disease, as well as an aid in deciding to stop antibiotics in patients with suspected/confirmed sepsis. It should not be used in isolation, i.e. without incorporating other clinical & lab data. Cannot be used in localized infections, e.g. cellulitis, meningitis. Cannot distinguish between infection and colonization, e.g. asymptomatic bacteriuria vs. UTI. Should not be used to alter accepted management of documented infections, e.g. pyelonephritis, Staphylococcus aureus bacteremia, etc. NOTE: Use of PCT will be audited by the Antimicrobial Stewardship Team and feedback to providers on appropriateness will be performed on an ongoing basis. PCT is a precursor of calcitonin and is thought to increase during bacterial infections as a result of bacterial blockade of calcitonin synthesis. In patients with bacterial infections it rises rapidly (detectable within 2-4 hours and peaks within 6-24 hours) and declines with control of infection. Unlike many other inflammatory biomarkers (e.g. C-reactive protein, ESR) PCT is not elevated in most non-infectious processes or non-bacterial infections. It is undetectable in healthy patients.
Sex Hormone Binding Globulin	SHBG may be useful in the differential diagnosis of hirsutism and in the assessment of bioavailable testosterone.
Vitamin D, 25-OH Total	This assay is used to diagnose vitamin D deficiency and aids in the differential diagnosis of hypo and hypercalcemia. Increased vitamin D levels may lead to hypertension, nephrolithiasis, and metastatic calcifications.
PTH	PTH is requested in the investigation of hyper and hypocalcemia. In addition it is usually requested prior to and during parathyroid surgery. A significant difficulty with parathyroid surgery is the possibility of missing an ectopic hyperfunctioning gland. Prior to surgery a baseline PTH level is drawn. If the PTH does not decrease by 50%, the surgeon may first send a frozen section to confirm that parathyroid tissue was indeed removed, and based on this result explore for an undetected enlarged gland. In most cases intra-operative PTH testing will save surgical time and minimize the need for follow-up surgery.

Infectious Disease	
SARS-CoV-2 IgG	The SARS-CoV-2 IgG assay is designed to detect immunoglobulin class G (IgG) antibodies to the nucleocapsid protein of SARS-CoV-2 in serum and plasma from individuals who are suspected to have had coronavirus disease (COVID-19) or in serum and plasma of subjects that may have been infected by SARS-CoV-2. COVID-19 is defined as illness caused by a novel coronavirus now called severe acute respiratory syndrome coronavirus 2 (SARSCoV-2, formerly called 2019-nCoV), which was first identified in December 2019 during an outbreak of respiratory illness cases in China.1 On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic.2 The incubation period of COVID-19 ranges between 1 and 14 days, with the majority of cases manifesting within 3 to 5 days. The most common symptoms of COVID-19 are fever, tiredness, dry cough, and difficulty breathing. A severe acute respiratory distress syndrome (ARDS) may develop.3 Reported case fatality rates depend on geographic location,4 age, and comorbidities. The causative agent of COVID-19 is a beta coronavirus and belongs to a family of viruses that may cause respiratory symptoms ranging from common cold to severe pneumonia. These viruses are common in animals worldwide and may eventually transfer to humans, as has likely happened with SARS-CoV-2.

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AdvixeDx SARS-CoV-2-IgG II	Provide evidence of past exposure to SARS-CoV-2. Most individuals diagnosed with COVID-19 seroconvert within 3 weeks of exposure to the virus. If a specimen is collected too early (i.e. prior to seroconversion), the test will yield a negative result. Provide evidence of antibody responsiveness to COVID-19 vaccination. It is not recommended to test for spike-specific antibodies until at least 3 weeks post-vaccination. The SARS-CoV-2 IgG assay is not a diagnostic test. Direct viral detection assays that employ molecular methods such as nucleic acid amplification, are the only laboratory tests that are diagnostic for COVID-19. IgG results should not be used to make decisions on infection status
Syphilis	The reverse algorithm for syphilis testing at Beaumont employs the use of an automated immunoassay platform to detect IgG and IgM antibody (i.e. total antibody) against Treponema pallidum, the causative agent of syphilis. Specimens that are nonreactive for Syphilis Total Antibody demonstrate no serological evidence of a past syphilis infection (i.e. syphilis screen negative). Specimens that test reactive for syphilis total antibody are automatically reflexed to RPR (Rapid Plasma Reagin) testing. Lastly, if the Syphilis Total Antibody and RPR results are discordant (i.e. syphilis total antibody, reactive, RPR nonreactive), the specimen is tested by TP-PA (Treponema pallidum particle agglutination) to adjudicate the discordant results.
HCV	The hepatitis C antibody assay can assist in the diagnosis of chronic Hepatitis C infections. The incubation period is approximately 50 days (range, 15-150 days). HCV antibody tests cannot detect acute hepatitis C infection because seroconversion may not occur for 8-16 weeks after exposure. Anti-HCV invariably becomes positive later in the course of the disease. Patients with initially seronegative samples should be retested in 3-6 months.
HBsAB	This assay aids in the diagnosis of Hepatitis B **Immune Status.**
HBCM	This assay aids in the diagnosis of acute or recent (usually six months or less) hepatitis B viral infection.IgM anti-HBc arises early in the illness of patients with acute hepatitis B, but it rapidly decreases in titer. HBV core IgM levels are generally not detectable 6 - 24 months after the onset of illness. The incubation period for hepatitis B is approximately 70 days (range, 30 - 180 days).
HBCT	Patients with hepatitis B may present with fatigue, poor appetite, fever, vomiting and occasionally joint pain, hives or rash. Urine may become darker in color, and then jaundice (a yellowing of the skin and whites of the eyes) may appear. Patients may also be asymptomatic or experience only a few symptoms. The incubation period for hepatitis B is approximately 70 days (range, 30-180 days).
HAVM	This assay is a qualitative procedure for detecting the presence or absence of hepatitis A virus IgM in serum and plasma specimens. The HAV IgM test is used as an aid in the diagnosis of an acute or recent (usually six months or less) hepatitis A viral infection. This test should be ordered when acute Hepatitis A infection is suspected. IgM antibodies are present at the onset of symptoms and peak approximately 4 weeks later. IgM antibodies usually disappear 3 - 6 months after the onset of disease. The presence of HAV- specific IgM in serum indicates a current or recent infection. The incubation period is 10 - 50 days with a mean incubation time of 1 month. The symptoms of hepatitis A may include fatigue, poor appetite, fever and vomiting. Urine may become darker in color, and then jaundice may appear. The disease is rarely fatal and most people recover in a few weeks without any complications. Infants and young children tend to have very mild symptoms and are less likely to develop jaundice than older children and adults.
HBSAG	HBsAg assay is used to aid in the diagnosis of hepatitis B, to monitor the status of infected individuals (i.e., whether the patient has resolved infection or has become a chronic carrier of the virus), and to evaluate the efficacy of anti-viral drugs. The CDC recommends a prenatal screening of all pregnant women so that newborns from HBV carrier mothers may obtain prophylactic treatment. The incubation period for hepatitis B is approximately 70 days (range, 30 - 180 days). HBsAg appears in the serum 2-7 weeks before the onset of symptoms. It usually persists in the blood throughout the illness and disappears with convalescence.
HIV	The initial screen is a 4th generation assay that detects both HIV-1 p24 antigen and antibodies to HIV-1 (groups M and O) and HIV-2. The new screen will detect acute HIV infection, on average 7 to 10 days earlier than the previously used antibody-only screen. Positive screen confirmation antibody testing to distinguish HIV-1 from HIV-2 will be performed in-house within 24 hours of initial testing. Western blots (currently a send-out test) will no longer be ordered. Rarely, additional molecular-based confirmation testing for HIV-1 and/or HIV-2 will be performed (Send Out) as delineated in the Automatec Chemistry algorithm. All test results will be included in a single report with a final interpretation. HIV-1 IgG is first detectable 3-12 weeks after infection in nearly all cases except neonates. Once established, HIV antibody levels usually persist throughout the lifetime of the patient. The presence of antibody does not imply immunity to the virus but rather, that the patient is assumed to be infected, and infectious. Little is known about the antibody response to HIV-2 infection. The response is presumed to be similar to HIV-1.

Assay	Method	Sample Type	Reagent On-board Stability (Days)	Reagent Prep	Calibrator	Calibration Frequency	Reagent Storage
Immnuoassay							
BHCG	Chemiluminescence	Serum	30	Liquid, Ready to Use	BHCG Cals	New Lot	2-8°C
Cortisol	Chemiluminescence	Serum	30	Liquid, Ready to Use	Cortisol Cals	New Lot	2-8°C
CPEP	Chemiluminescence	Serum	30	Liquid, Ready to Use	C-Pep Cals	New Lot	2-8°C
DHEA-S	Chemiluminescence	Serum	30	Liquid, Ready to Use	DHEA-S Cals	New Lot	2-8°C
Estradiol	Chemiluminescence	Serum	30	Liquid, Ready to Use	Estradiol Cals	New Lot	2-8°C
Ferritin	Chemiluminescence	Serum	30	Liquid, Ready to Use	Ferritin Cals	New Lot	2-8°C
Folate	Chemiluminescence	Serum	30	Liquid, Ready to Use	Folate Cals	New Lot	2-8°C
Free PSA	Chemiluminescence	Serum	30	Liquid, Ready to Use	Free PSA Cals	New Lot	2-8°C
Free T3	Chemiluminescence	Serum	30	Liquid, Ready to Use	FT3 Cals	New Lot	2-8°C
Free T4	Chemiluminescence	Serum	30	Liquid, Ready to Use	FT4 Cals	New Lot	2-8°C
FSH	Chemiluminescence	Serum	30	Liquid, Ready to Use	FSH	New Lot	2-8°C
Insulin	Chemiluminescence	Serum	30	Liquid, Ready to Use	Insulin Cals	New Lot	2-8°C
PTH	Chemiluminescence	EDTA Plasma, Serum	30	Liquid, Ready to Use	iPTH Cals	New Lot	2-8°C
LH	Chemiluminescence	Serum	30	Liquid, Ready to Use	LH Cals	New Lot	2-8°C
Procalcitonin	Chemiluminescence	Li Heparin	25	Liquid, Ready to Use	B.R.A.H.M.S PCT Cals	New Lot	2-8°C
Progesterone	Chemiluminescence	Serum	30	Liquid, Ready to Use	Progest Cals	New Lot	2-8°C
Prolactin	Chemiluminescence	Serum	30	Liquid, Ready to Use	Prolactin Cals	New Lot	2-8°C

Sex Hormone Binding Gobulin	Chemiluminescence	Serum	30	Liquid, Ready to Use	SHBG Cals	New Lot	2-8°C
Testosterone	Chemiluminescence	Serum	30	Liquid, Ready to Use	2nd Generation Testosterone Cals	New Lot	2-8°C
Total PSA	Chemiluminescence	Serum	30	Liquid, Ready to Use	Total PSA Cals	New Lot	2-8°C
TSH	Chemiluminescence	Serum	30	Liquid, Ready to Use	TSH Cals	New Lot	2-8°C
Vitamin B12	Chemiluminescence	Serum	26	Liquid, Ready to Use	B12 Cals	New Lot	2-8°C
Vitamin D, 25-OH, Total	Chemiluminescence	Serum	30	Liquid, Ready to Use	VitD 25OH Cals	30 days or New Lot	2-8°C
Cardiac Markers							
BNP	Chemiluminescence	EDTA Plasma	30	Liquid, Ready to Use	BNP Cals	New Lot	2-8°C
Homocysteine	Chemiluminescence	Serum	30	Liquid, Ready to Use	HCY Cals	New Lot	2-8°C
Myoglobin	Chemiluminescence	Serum	30	Liquid, Ready to Use	Stat Myoglobin Cals	New Lot	2-8°C
Troponin	Chemiluminescence	Li Heparin	30	Liquid, Ready to Use	Stat Troponin-I Cals	New Lot	2-8°C
High Sensitivity Troponin I	Chemiluminescence	EDTA Plasma	30	Liquid, Ready to Use	hs_TnI_STAT Cals	New Lot	2-8°C
Infectious Disease							
SARS-CoV-2 IgG	Chemiluminescence	Serum	7	Liquid, Ready to Use	CoV-2 IgG Cal	New Lot	2-8°C
AdviseDx SARS-CoV-2 IgGII	Chemiluminescence	Serum	30	Liquid, Ready to Use	AdviseDx CoV-2 IgG II Cal	New Lot	2-8°C
Syphilis	Chemiluminescence	Serum	30	Liquid, Ready to Use	Syphilis Cal	New Lot	2-8°C
Anti-HAV IgG	Chemiluminescence	Serum	30	Liquid, Ready to Use	HAVAB-G Cals	New Lot	2-8°C
Anti-HAV IgM	Chemiluminescence	Serum	30	Liquid, Ready to Use	HAVAB-M Cals	New Lot	2-8°C
Anti-HBc IgM	Chemiluminescence	Serum	30	Liquid, Ready to Use	CORE-M Cals	New Lot	2-8°C

Anti-HBc Total	Chemiluminescence	Serum	30	Liquid, Ready to Use	CORE Cals	New Lot	2-8°C
Anti-HBs	Chemiluminescence	Serum	30	Liquid, Ready to Use	AUSAB Cals	New Lot	2-8°C
Anti-HCV	Chemiluminescence	Serum	30	Liquid, Ready to Use	Anti-HCV Cals	New Lot	2-8°C
HBsAG	Chemiluminescence	Serum	30	Liquid, Ready to Use	HBsAg Qual Cals	New Lot	2-8°C
HIV Ag/Ab	Chemiluminescence	Serum	30	Liquid, Ready to Use	HIV Ag/Ab Cals	New Lot	2-8°C
Tumor Markers							
AFP Tumor Marker	Chemiluminescence	Serum	30	Liquid, Ready to Use	AFP Cals	New Lot	2-8°C
CA 125	Chemiluminescence	Serum	30	Liquid, Ready to Use	CA 125 Cals	New Lot	2-8°C
CA 15.3	Chemiluminescence	Serum	30	Liquid, Ready to Use	CA 15-3 Cals	New Lot	2-8°C
CA 19.9	Chemiluminescence	Serum	30	Liquid, Ready to Use	CA 19-9xr Cals	New Lot	2-8°C
CEA	Chemiluminescence	Serum	30	Liquid, Ready to Use	CEA Cals	New Lot	2-8°C

Diluents

	Stability	Reagent Storage
Multi-Assay Manual Diluent	Until Exp Date	RT
AUSAB Specimen Diluent	Until Exp Date	2-8°C
HBsAG Qualatative Confimatory Manual Diluent	Until Exp Date	2-8°C

Bulk Solutions

	Stability	Reagent Storage
Trigger Solution	Until Exp Date	RT
Pre-Trigger Solution	Until Exp Date	2-8°C
Probe Conditioning Solution	Until Exp Date	2-8°C
Arm Buffer Solution	Until Exp Date	RT
Concentrated Wash Solution	Until Exp Date	RT

Note: Class A Glassware is not required to prepare bulk solutions.

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i1000/i2000 Refrigerated Calibrators

Test	Abbott Calibrator Name	Preparation	Open Stability	Storage Temp After Opening	Number of Levels
BHCG	BHCG Cals	Ready to Use	Until Exp Date	2-8° C	6
Free PSA	Free PSA Cals	Ready to Use	Until Exp Date	2-8° C	2
Total PSA	Total PSA Cals	Ready to Use	Until Exp Date	2-8° C	2
Free T4	FT4 Cals	Ready to Use	Until Exp Date	2-8° C	6
TSH	TSH Cals	Ready to Use	Until Exp Date	2-8° C	2
Vitamin B12	B12 Cals	Ready to Use	30 Days	2-8° C	6
Ferritin	Ferritin Cals	Ready to Use	Until Exp Date	2-8° C	2
Free T3	FT3 Cals	Ready to Use	Until Exp Date	2-8° C	6
Troponin	Stat Troponin-I Cals	Ready to Use	Until Exp Date	2-8° C	6
Homocysteine	HCY Cals	Ready to Use	Until Exp Date	2-8° C	6
Myoglobin	Stat Myoglobin Cals	Ready to Use	Until Exp Date	2-8° C	6
CA 19-9	CA 19-9xr Cals	Ready to Use	Until Exp Date	2-8° C	6
Estradiol	Estradiol Cals	Ready to Use	Until Exp Date	2-8° C *Sensitive to Light*	6
FSH	FSH Cals	Ready to Use	Until Exp Date	2-8° C	2
LH	LH Cals	Ready to Use	120 Days	2-8° C	6
Insulin	Insulin Cals	Ready to Use	Until Exp Date	2-8° C	6
AFP Tumor Marker	AFP Cals	Ready to Use	Until Exp Date	2-8° C	6
CA 125	CA 125 II Cals	Ready to Use	Until Exp Date	2-8° C	6
CA 15-3	CA 15-3 Cals	Ready to Use	Until Exp Date	2-8° C	6
C-Peptide	C-Pep Cals	Ready to Use	Until Exp Date	2-8° C	6
DHEA-S	DHEA-S Cals	Ready to Use	Until Exp Date	2-8° C	6
CEA	CEA Cals	Ready to Use	Until Exp Date	2-8° C	2
Vitamin D 25-OH	VitD 25OH Cals	Ready to Use	Until Exp Date	2-8° C	6

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i1000/i2000 Frozen Calibrators

Test	Abbott Calibrator Name	Preparation	Open Stability	Storage Temp After Opening	Number of Levels
BNP	BNP Cals	Thaw completley before use	90 Days	2-8° C	6
Folate	Folate Cals	Thaw @ RT for 45 mins or until completely thawed.	Good for 3 thaw cycles	Frozen *Sensitive to Light*	6
Testosterone	2nd Generation Testosterone Cals	Thaw @ RT for 90-120 Mins	90 Days	2-8° C	6
Progesterone	Progest Cals	Thaw @ RT for 1-2 HRS	21 Days	2-8° C	2
Cortisol	Cortisol Cals	Thaw @ RT for 45-60 Mins	90 Days	2-8° C	6
PCT	B.R.A.H.M.S PCT Cals	Thaw @ RT 30-60 Mins	Good for 3 thaw cycles	Frozen	6
PTH	iPTH Cals	Thaw @ RT for 30-60 mins	30 days	2-8° C	6
Prolactin	Prolactin Cals	Thaw @ RT for 1-2 HRS	60 Days	2-8° C	2
SHBG	SHBG Cals	Thaw @ RT for 30 - 60 mins	Good for 3 thaw cycles	Frozen	6
hs Troponin I	STAT High Sensitivity Troponin-I Cals	Remove from carton and allow to stand at RT until completely thawed (90 to 120 minutes)	Good for 3 thaw cycles	Frozen	6

i1000/i2000 Infectious Disease Calibrators

Test	Abbott Calibrator Name	Preparation	Open Stability	Storage Temp After Opening	Number of Levels
SARS-CoV IgG	CoV-2 IgG Cal	Thaw completley before use	60 Days	2-8° C	1
AdviseDx SARS-CoV IgG II	AdviseDx SARS-CoV IgG II Cal	Thaw completley before use	30 Days	2-8° C	6
Syphilis	Syphilis Cal	Ready to Use	Until Exp Date	2-8° C	1
Anti-HAV IgG	HAVAB-G Cals	Ready to Use	Until Exp Date	2-8° C	1
Anti-HAV IgM	HAVAB-M Cals	Ready to Use	Until Exp Date	2-8° C	1
Anti-HBc IgM	CORE-M Cals	Ready to Use	Until Exp Date	2-8° C	2
Anti-HBc Total	CORE Cals	Ready to Use	Until Exp Date	2-8° C	1
Anti-HBs	AUSAB Cals	Ready to Use	Until Exp Date	2-8° C	6

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Anti-HCV	Anti-HCV Cals	Ready to Use	Until Exp Date	2-8° C	1
HBsAG	HBsAg Qual Cals	Ready to Use	Until Exp Date	2-8° C	2
HIV Ag/Ab	HIV Ag/Ab Combo Cal	Ready to Use	Until Exp Date	2-8° C	1

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REFERENCE RANGES

TEST	AGE	Low	High
AFP, NON-PREGNANT (ng/mL)			
	0 -< 1 MONTH		> 2000.0
	1 - < 3 MONTHS	10.0	1359.0
	3 - < 6 MONTHS	4.0	275.0
	6 MONTHS - < 1 YEAR	3.0	148.0
	1 - < 3 YEARS	3.0	21.0
	3 YEARS - ADULT		< 8.5
B12, VITAMIN (pg/mL)			
		271	1000
BETA HCG, TOTAL (mIU/mL)			
			≤ 5
BNP (pg/mL)			
			≤ 100
CA 15-3 (U/mL)			
			< 32.0
CA 19-9 (U/mL)			
			≤ 37.0
CA 125 (U/mL)			
			≤ 35
CEA (ng/mL)			
			≤ 3.0
CORTISOL (ug/dL)			
Random, AM, PM		2.9	19.4
Dexamethasone Supression, Overnight			< 1.8
C-PEPTIDE (ng/mL)			
		0.8	5.2
DHEAS (ug/dL)			
MALES		49	592
FEMALES		30	512
ESTRADIOL (E2) (pg/mL)			
MALES		11	44
FEMALES	FOLLICULAR	21	251
	MID-CYCLE	38	649
	LUTEAL	21	312
	POST-MENOPAUSAL		≤ 28

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FERRITIN (ng/mL)			
	MALES	14	338
	FEMALES	12	207
FOLATE (ng/mL)			
			> 5.4
FREE T3 (pg/mL)			
		1.7	3.7
FREE T4 (ng/dL)			
	NON-PREGNANT ADULT	0.7	1.5
	PEDIATRICS (0 TO 9 DAYS)	0.5	1.7
	PREGNANCY		
	1ST TRIMESTER	0.7	1.5
	2ND TRIMESTER	0.5	1.0
	3RD TRIMESTER	0.5	1.0
FSH (mIU/mL)			
	MALES	1.0	12.0
	FEMALES FOLLICULAR	3.0	8.1
	MID-CYCLE	2.6	16.7
	LUTEAL	1.4	5.5
	POST MENOPAUSAL	26.7	133.4
High Sensitivity Troponin-I (ng/L)			
	MALES NORMAL		≤ 35
	INDETERMNATE		36-199
	SUGGESTIVE OF MYOCARDIAL DAMAGE		≥ 200
	FEMALES NORMAL		≤ 17
	INDETERMNATE		18-199
	SUGGESTIVE OF MYOCARDIAL DAMAGE		≥ 200
HOMOCYSTEINE (umol/L)			
		4	10
INSULIN (uU/mL)			
	Fasting		<26
	Insulin, 2hr Post Glucola	22	71
LH (mIU/mL)			
	MALES	0.6	12.1
	FEMALES FOLLICULAR	1.8	11.8
	MID-CYCLE	7.6	89.1
	LUTEAL	0.6	14.0
	POST MENOPAUSAL	5.2	62.0
MYOGLOBIN (ng/mL)			
			< 98.0

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PROCALITONIN (ng/mL)			
			≤ 0.25
PROGESTERONE (ng/mL)			
MALES			≤ 0.2
FEMALES	FOLLICULAR	0.1	0.3
	LUTEAL	1.2	15.9
	POST MENOPAUSAL		< 0.2
	PREGNANCY		
	1ST TRIMESTER	2.8	147.3
	2ND TRIMESTER	22.5	95.3
	3RD TRIMESTER	27.9	242.5
PROLACTIN (ng/mL)			
MALES		2.0	18.0
FEMALES	NON-PREGNANT	3.0	30.0
	PREGNANT	10.0	208.0
	POST MENOPAUSAL	2.0	20.0
PTH (pg/mL)			
		8	72
TESTOSTERONE (ng/dL)			
	18 - 39 YEARS	240	1080
	40 - 59 YEARS	240	890
	60 AND OLDER	240	720
PSA, TOTAL (ng/mL)			
			≤ 2.50
PSA, FREE (ng/mL)			
			N/a
	% FREE		≥ 24 %
TSH (uIU/mL)			
	CORD BLOOD	1.00	39.00
	1 YEAR - ADULT	0.40	4.50
	PEDIATRIC RANGES		
	0 - 2 DAYS	3.20	34.60
	3- 4 DAYS	0.70	15.40
	5 DAYS - < 1 MONTH	1.70	9.10
	1 MONTH - < 1 YEAR	0.80	8.20
	PREGNANCY		
	1ST TRIMESTER	0.26	2.66
	2ND TRIMESTER	0.55	2.73
	3RD TRIMESTER	0.43	2.91

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TROPONIN-I (ng/mL)			
	NORMAL		≤ 0.03
	INDETERMNATE		0.04 - 0.29
	SUGGESTIVE OF MYOCARDIAL DAMAGE		≥ 0.30
SHBG (nmol/L)			
PEDIATRICS			
	0 DAYS - < 1 MONTH	14	120
	1 MONTH - 12 MONTHS	36	229
	13 MONTHS - 7 YEARS	42	189
	8 YEARS - 10 YEARS	26	162
	11 YEARS - 12 YEARS	15	108
	13 YEARS - 14 YEARS	11	98
	15 YEARS - 16 YEARS (FEMALES)	10	84
	17 YEARS - 18 YEARS (FEMALES)	10	155
	15 YEARS - 18 YEARS (MALES)	10	50
ADULT			
	MALES	11	78
	FEMALES	12	137
VITAMIN D (25-OH) (ng/mL)			
		30	100

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REFERENCE RANGES - Infectious Disease

Hepatitis A Antibody, IgG		
	<1.00 S/CO	Nonreactive
Hepatitis A Antibody, IgM		
	0.00-0.79 S/CO	Nonreactive
Hepatitis B Core Antibody, IgM		
	0.00-0.79 Index	Nonreactive
Hepatitis B Core Antibody, Total		
	0.00-0.99 Index	Nonreactive
Hepatitis B Surface Antibody		
	<12.00 mIU/mL	
Hepatitis B Surface Antigen		
	0.00-0.99 Index	Nonreactive
Hepatitis C Virus Antibody		
	0.00-0.79 Index	Nonreactive
HIV		
	0.00-0.99 Index	Nonreactive
SARS CoV-2 IgG		
	<1.4 S/CO	Negative
SARS CoV-2 IgG II		
	<50.0 AU/mL	Negative
Syphilis Total Antibody		
	<1.00 S/CO	Nonreactive

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Analytical Measuring Ranges
IMMUNOASSAY

ASSAY	UNITS	LOW	HIGH	OnBoard Dilution	Extended Range	Diluent/ Dilution	Maximim Reportable
AFP TUMOR MARKER	ng/mL	2.0	2000.0	1:10	20000.0	Multi assay diluent	>180000*
B12, VITAMIN	pg/mL	146	2000				>2000
BNP	pg/mL	10	5000	1:5	25000		>25000
C PEPTIDE	ng/mL	0.1	30.0	1:10	300.0		>300.0
CA 125	U/mL	1	1000	1:10	10000		>10000
CA 15-3	U/mL	0.5	800.0	1:5	4000.0		>4000.0
CA 19-9	U/mL	2.0	1200.0	1:10	12000.0	Multi assay diluent	>12000000*
CA 19-9, FLUID	U/mL	2.0	1200.0	1:10	12000.0		>12000000*
CEA	ng/mL	0.5	1500.0	1:10	15000.0		>15000.0
CEA, Pancreatic	ng/mL	0.5	1500.0	1:10	15000.0		>15000.0
CoV-2 IgG II	AU/mL	50.0	25000.0	1:2	50000.0		>50000.0
CORTISOL	ug/dL	1.0	59.8	1:2	119.6	Calibrator A	>1100.0*
DHEA-S	ug/dL	3	1500				>1500
ESTRADIOL	pg/mL	10	1000	1:5	5000		>5000
FERRITIN	ng/mL	1	2000	1:20	40000		>40000
FOLATE	ng/mL	1.6	20.0				>20.0
FREE T3	pg/mL	1.5	20.0				>20.0
FREE T4	ng/dL	0.4	5.0				>5.0
FSH	mIU/mL	0.5	150.0	1:5	750.0		>750.0
Hepatitis B Surface Antibody	mIU/mL	<8.00	1000.0				>1000.0
HBSAG Conf	%					HBSAG Conf Diluent	Manual 1:500 Manual 1:20000
High Sensitivity TnI	ng/L	4	5000				>5000
HOMOCYSTEINE	umol/L	1	50				>50
INSULIN	uU/mL	1	300	1:2	600		>600
LH	mIU/mL	0.1	250.0	1:4	1000.0		>1000.0
MYOGLOBIN	ng/mL	1.0	1200.0	1:10	12000.0		>12000.0
PROCALCITONIN	ng/mL	0.02	100.00				>100.00
PROGESTERONE	ng/mL	0.1	40.0	1:10	400.0		>400.0
PROLACTIN	ng/mL	0.6	200.0	1:10	2000.0		>2000.0
PSA, FREE	ng/mL	0.02	30.00				>30.00
PSA, TOTAL	ng/mL	0.10	100.00	1:10	1000.00		>1000.00
PTH	pg/mL	4	2500				>2500
SHBG	nmol/L	2	250	1:5	1250		>1250
TESTOSTERONE	ng/dL	5	1009.4	1:4	1500		>1500**
TOTAL BETA HCG	mIU/mL	1	15000	1:15	225000	Multi Assay Manual Diluent x30 then x75, if needed	>1125000*
TROPONIN-I	ng/mL	0.01	50.00				>50.00
TSH	uIU/mL	0.01	100.00	1:5	500.00		>500.00
VITAMIN D, 25-OH Total	ng/mL	4	155				>155

*Requests for CORT, AFP, hCG, and CA199 are diluted to endpoint. Results above the stated maximum reportable are diluted in duplicate before reporting. Dilutions should agree within 10%

** Verify dilution condition is STD before reporting Testo as "less than"

Dilution Guide		
Dilution - Program at the instrument	DILUENT Volume	SAMPLE Volume
X2	100uL	100uL
X5	400uL	100uL
X10	900uL	100uL
X20	950uL	50uL
X30	580uL	20uL
X75	740uL	10uL
X100	990uL	10uL

For very high samples, a manual serial dilution may be required.			
Tube	Amount of Diluent	Amount of sample	dilution
1	450 uL	50 uL of straight sample	X10
2	450 uL	50 uL from Tube 1	X100
3	450 uL	50 uL from Tube 2	X1,000
4	450 uL	50 uL from Tube 3	X10,000
5	450 uL	50 uL from Tube 4	X100,000

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HEMOLYSIS	Cancel and request a redraw at Hemolysis index 500 and above unless otherwise noted.

ABBOTT	Comment	Hemolysis Value
VB12	Cancel at 200	200
Folate	Cancel at 200	200
Cortisol	Cancel at 1500	1500

LIPEMIA	Airfuge ALL samples at 200

FLUIDS	Do not cancel the following fluids based on Hemolysis index
ABBOTT	
CA 19-9	
CEA	
HCG	
AFP	

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Test by Campus

9/11/2023

Assay	Dearborn	Royal Oak	Grosse Pointe	Troy	Canton	Taylor	Trenton	Wayne	Farmington Hills	Lenox	Livonia
Anti-HAV IgG (HAVAB-G)	X	X									
Anti-HAV IgM (HAVAB-M)	X	X									
Anti-HBc (Core)	X	X									
Anti-HBc IgM (Core-M)	X	X									
Anti-HCV (HCV 2.0)	X	X									
B12	X	X	X	X					X		
HCG	X	X	X	X	X	X	X	X	X	X	X
BNP	X	X	X	X	X	X	X	X	X	X	X
CA 125	X	X									
CA 15-3	X	X									
CA 19-9	X	X									
CEA	X	X									
Cortisol	X	X		X							
DHEAS		X									
Estradiol	X	X									
Ferritin	X	X	X	X					X		
Folate	X	X	X	X					X		
Free T3	X	X		X							
Free T4	X	X	X	X		X	X	X	X		
FSH	X	X									
HBsAg Qual	X	X									
HIV Combo	X	X	X	X					X		
Homocysteine	X	X									
Insulin	X	X									
PTH	X	X	X	X					X		
LH	X	X									
Myoglobin	X	X									
Progesterone	X	X									
Prolactin	X	X									
PSA (free)		X									

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Test by Campus

9/11/2023

Assay	Dearborn	Royal Oak	Grosse Pointe	Troy	Canton	Taylor	Trenton	Wayne	Farmington Hills	Lenox	Livonia
PSA (total)	X	X	X	X					X		
Testosterone	X	X									
High Sensitivity TnI	X	X	X	X					X	X	X
Troponin-I					X	X	X	X			
TSH	X	X	X	X		X	X	X	X		
Vitamin D	X	X	X	X					X		
AFP	X	X									
Anti-HBs (Ausab)	X	X									
C-Peptide		X									
HBsAg Confirmatory	X	X									
Procalcitonin	X	X	X	X		X	X	X	X		
SHBG		X									
Syphilis	X	X	X	X					X		
SARS-CoV-2 IgG		X									
SARS-CoV-2 IgG II	X	X									

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Specimen Stability

9/8/2023

TEST	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
BHCG	8 hrs	7 days	7 days	2 hrs			24 hrs	7 days	12 months
Cortisol	8 hrs	7 days	7 days	2-4 hrs					
CPEP			7 days						
DHEA-S	2 hrs	7 days	2 months	2 hrs					
Estradiol	2-4 hrs	7 days	7 days	2-4 hrs					
Ferritin	2-4 hrs	7 days	7 days	2-4 hrs					
Folate	2-4 hrs	2 days	7 days	2-4 hrs					
Free PSA	2-4 hrs	7 days	7 days	2-4 hrs					
Free T3	2-4 hrs	7 days	7 days	2-4 hrs					
Free T4	2-4 hrs	7 days	7 days	2-4 hrs					
FSH	2-4 hrs	7 days	7 days	2-4 hrs					
Insulin	2 hrs	7 days	3 months	2 hrs					
PTH (EDTA)	4 Hrs	48 hrs	2 months				8 hrs	72 hrs	
LH	2-4 hrs	7 days	7 days	2-4 hrs				72 hrs	
Procalcitonin (Li Heparin)							2 hrs	48 hrs	8 weeks
Progesterone	2-4 hrs	48 hrs	7 days	2-4 hrs					
Prolactin	2-4 hrs	7 days	7 days	2-4 hrs					
Sex Hormone Binding Gobulin	2 hrs	7 days	2 months	2 hrs					
Testosterone	2-4 hrs	7 days	7 days	2-4 hrs					
Total PSA	8 hrs	5 days	7 days	2-4 hrs					
TSH	2-4 hrs	7 days	7 days	2-4 hrs					
Vitamin B12	2-4 hrs	7 days	7 days	2-4 hrs					

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Specimen Stability

9/8/2023

TEST	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
Vitamin D, 25-OH, Total	2 hrs	7 days	3 months	2 hrs					
Cardiac Markers									
BNP (EDTA)							4 hrs	24 hrs	≤ 3 months
Homocysteine	2-4 hrs	48 hrs	13 weeks	2-4 hrs					
Myoglobin	2-4 hrs	7 days	7 days	2-4 hrs			8 hrs	72 hrs	30 days
High Sensitivity TnI (EDTA plasma)							unspun: 2hrs spun: 24 hrs	unspun: 2 hrs spun: 5 days	
Troponin (Li Heparin)							2 hrs	48 hrs	8 weeks
Infectious Disease									
SARS-CoV-2 IgG (EDTA)	2 days	7 days					2 days	7 days	
AdviseDx SARS-CoV-IgG II (EDTA)	2 days	7 days							
Syphilis	12 hours	7 Days	1 year	2 hours					
Anti-HAV IgG	2-4 hrs	7 days	7 days	2-4 hrs					
Anti-HAV IgM (EDTA)	2-4 hrs	7 days	7 days	2-4 hrs			12 hrs	7 days	7 days
Anti-HBc IgM (EDTA)	2-4 hrs	7 days	7 days	2-4 hrs			12 hrs	7 days	7 days
Anti-HBc Total (EDTA)	2-4 hrs	72 hrs	7 days	2-4 hrs			12 hrs	72 hrs	7 days
Anti-HBs (EDTA)	2-4 hrs	7 days	7 days	2-4 hrs			12 hrs	7 days	7 days

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Specimen Stability

9/8/2023

TEST	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
Anti-HCV (EDTA)	2-4 hrs	7 days	7 days	2-4 hrs			12 hrs	7 days	7 days
HBsAG (EDTA)	2-4 hrs	7 days	7 days	2-4 hrs			12 hrs	7 days	7 days
HIV Ag/Ab	2-4 hrs	7 days	7 days	2-4 hrs					
Tumor Markers									
AFP Tumor Marker	4 hrs	7 days	1 year	2-4 hrs	24 hrs				
CA 125	2 hrs	7 days	7days	2 hrs					
CA 15.3	2-4 hrs	7 days	7 days	2-4 hrs					
CA 19.9	2-4 hrs	7 days	7 days	2-4 hrs					
CEA	2 hrs	7 days	2 months	2 hrs					

No Re-test

Assay	Negative	Equivocal	Hot Zone Positive	Possible Results
HAV IgG (S/CO)	<=0.99	*none*	>=1.00	Report as Reactive or Nonreactive
HAV IgM (S/CO)	<=0.79	0.80-1.20	>=1.21	Report as Reactive, Nonreactive or Equivocal
HBc IgM (S/CO)	<=0.79	0.80-1.20	>=1.21	Report as Reactive, Nonreactive or Equivocal
SARS CoV-2 IgG	<1.4	*none*	>=1.4	Report as Positive and Negative
SARS CoV-2 IgG II	<50.0	*none*	>=50.0	Report as numerical value AND Reactive or Nonreactive
Syphilis	<1.0	*none*	>=1.0	Report as Reactive or Nonreactive

Retest Required - Neat

Assay	Negative	*Re-test in Duplicate*	Hot Zone Positive	Possible Results
AUSAB (mIU/mL)	<=7.99	*8.00-11.99 Repeat in duplicate*	>=12.00	Report as numerical value

Retest Required - Neat

Assay	Negative	*Equivocal*	Positive/ Reactive	Possible Results
HBc Total (S/CO)	<=0.79	*0.80-1.20 Repeat ALL EQUIVOCAL results in duplicate*	>=1.21 Repeat ALL REACTIVE results in duplicate	2/3 ≥ 1.00 Report as Reactive 2/3 ≤ 1.00 Report as Nonreactive
HCV (S/CO)	<=0.79	*0.80-0.99 Repeat ALL GRAYZONE results in duplicate*	>=1.00 *Repeat ALL POSITIVE results in duplicate	Report as Reactive, Nonreactive or Equivocal
HIV (S/CO)	<=0.99	*none*	>=1.00 *Repeat ALL REACTIVE results in duplicate	Follow HIV workflow reference guide
HBsAg (S/CO)	<=0.99	*none*	>=1.00 *Repeat ALL REACTIVE results in duplicate and CONF	Follow HBsAg workflow reference guide - Report Reactive or Nonreactive

Confirmation - If Dilution is needed, use HBsAg Qual Confirmatory Manual Diluent and MIX WELL

Dilution	Dilution instructions	HBsAg C2 S/CO	% Neut	Final Interpretation
NEAT		*< 0.70*	Not applicable	**NOT CONFIRMED**
		< 10.00	< 50%	**NOT CONFIRMED**
		≥ 0.70	≥ 50%	**CONFIRMED**
		≥ 10.00	< 50%	***Repeat conf using 1:500 DIL***
DIL 1:500	Make a serial dilution Tube 1 (x10): 100 uL patient sample + 900 uL Diluent Tube 2 (x100): 100 uL of Tube 1 + 900 uL Diluent **Tube 3 (x500):** 200 uL of Tube 2 + 800 uL Diluent	< 0.70	Not applicable	**NOT CONFIRMED**
		≥ 0.70	> 50%	**CONFIRMED**
		≥ 0.70	< 50%	***Repeat conf using 1:20000 DIL***
DIL 1:20,000	Continue serial dilution Tube 4 (x5,000): 100 uL of Tube 3 + 900 uL Diluent **Tube 5 (x20,000):** 250 uL of Tube 4 + 750 uL Diluent	< 0.70	Not applicable	**NOT CONFIRMED**
		≥ 0.70	> 50%	**CONFIRMED**
		≥ 0.70	< 50%	**NOT CONFIRMED**

If the % Neutralization is < -15%, then the results should be considered invalid and the specimen should be retested by dilution. Perform the retest using the calculated assay (HBsAgQu %N) and both constituent assays (HBsAgQu C1 and HBsAgQu C2). If the 1:20,000 dilution is invalid, a new specimen should be obtained. The Confirmation requires about 250uL

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Fluid Guide

2/17/2023

Approved List of fluids for Abbott Architect Chemistry Analyzers

	CSF	Peritoneal	Pleural	Pancreatic
AFP	X			
BhCG	X			
CA 19-9		X	X	X
CEA				X

CSF for AFP and BhCG, and Peritoneal, Pleural, and Pancreatic fluid for CA19-9 have been validated on the Abbott Architect at the Royal Oak Campus. Pancreatic fluid for CEA has been validated at the Dearborn and Royal Oak Campuses. Refer to **Attachment C** for the reportable ranges.

Note: All Fluids with Chemistry tests requested are centrifuged before testing.

Reference Ranges and Clinical Significance

AFP	
CSF <2 ng/mL	Evaluates the presence of germ-cell tumors in the nervous system. CSF levels of AFP will also be elevated with brain metastases of testicular cancer.

BhCG	
CSF <3 mIU/mL	Aids in diagnosis of brain metastases of testicular cancer or extragonadal intracerebral germ tumors.

CA 19-9	
Peritoneal Fluid <35 U/mL	Useful initially, in the classification of an effusion as an exudate or a transudate. Measuring CA 19-9 in peritoneal fluid can be used as an adjunct to cytology to differentiate between malignancy-related ascites and benign causes of ascites formation. Do not use peritoneal fluid carbohydrate antigen CA 19-9 (CA 19-9) levels as absolute evidence of the presence or absence of malignant disease. The evaluation and diagnosis of malignancy-related ascites is based on the patient clinical history, ascites fluid analysis and imaging tests.
Pleural Fluid <37 U/mL	Useful initially, in the classification of an effusion as an exudate or a transudate.
Pancreatic Fluid <37 U/mL	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. CA 19-9 concentrations less than or equal to 37 U/mL indicate a low risk for a mucinous cyst, and are more consistent with serous cystadenoma or pseudocyst. However, very low concentrations should be viewed with caution since CA 19-9 is a modified Lewis(a) blood group antigen and may not be produced by Lewis non-secretors.

CEA	
Pancreatic	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. The higher the CEA concentration the more likely a cyst is a mucinous cyst with increased likelihood of malignancy. CEA greater than 200 ng/mL is very suggestive but not diagnostic of a mucinous cyst. Much lower CEA concentrations are usually seen with non-mucinous cysts. Results should be used in conjuction with clinical information, imaging studies, cytology, and pancreatic cyst tumor markers.