Attributes for the Beckman Coulter Access 2 Analyzer						
	[BNP]	[High sensitivity Troponin]				
Methodology/Reaction/Wavelength	Two-site immunoenzymatic ("sandwich")/ chemiluminescent	Two-site immunoenzymatic ("sandwich")/chemiluminescent				
Clinical Utility	Diagnosis and assessment of severity of congestive heart failure	Aids in the risk stratification of of patients with unstable angina or ailure non-ST segment elevation acute coronary syndromes				
Sample Type	EDTA Plasma EDTA Plasma (should not be used interchangeably)					
Specimen Stability						
Room Temp	7 hrs (plasma or whole blood)	4 hrs				
Refrigerated	24 hrs (plasma only)	48 hrs				
Frozen	Indefinite	6 months				
Patient/Sample Preparation	None	None				
Reagents	No preparation required	No preparation required				
Reagent Storage	2 °C to 10 °C	2 °C to 10 °C				
Calibration	Calibration is required every 28 days Six levels of calibrators are run in duplicate.	Calibration is required every 63 days Seven levels of calibrators are run in duplicate.				
Quality Control	Cardiac Markers Plus Control LT Level 1B and Level 3	Cardiac Markers Plus Control LT Level 1B and Level 3				
Calculations	N/A	N/A				
Interferences	Hemolysis – NSI	Hemolysis – NSI up to hemoglobin 400 mg/dL				
	Icterus - NSI	Icterus –NSI up to bilirubin 40 mg/dL				
	Lipemia – NSI *	Lipemia – NSI * up to triglycerides 3000 mg/dL				
Method Performance	Linear range of detection:	Linear range of detection:				
Specifications	1-5000 pg/mL	2.0 – 27,000 pg/mL				
Dilutions	Do not dilute, report as > 5000 pg/mL	Do not dilute, report as > 27,000 pg/mL				

• NSI – No Significant Interference.

• Quality Control material- run daily, with each new calibration, with each new reagent bottle loaded, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual.

• Calibration- the system must have a valid calibration before quality controls or patient samples can be tested. Frequency as specified, after parts replacements and/or maintenance procedures, when there are signs of possible deterioration are control values out of range.

 Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information.

 Refer to LabNet/Health Connect for Reference Ranges and Critical Limits. <u>http://kpnet.kp.org:81/california/scpmg/labnet/</u>
 \*All samples with lipemia index >3 should be ultracentrifuged by airfuge.

\*\* All immunoassay assays are affected by the present of heterophile antibodies.

Attributes for the Beckman Coulter Access 2 Analyzer				
	[HCG]			
Methodology/Reaction/Wavelength	Two-site immunoenzymatic ("sandwich")/ chemiluminescent			
Clinical Utility	Determining pregnancy, ectopic pregnancy or impending spontaneous abortion			
Sample Type	Lithium Heparin Plasma Serum			
Specimen Stability				
Room Temp	8 hrs			
Refrigerated	48 hrs			
Frozen	6 months			
Patient/Sample Preparation	None Post-menopausal patients can show slight elevation up to 12 mIU/mL			
Reagents	No preparation required			
Reagent Storage	2 °C to 10 °C			
Calibration	Calibration is required every 28 days Six levels of calibrators are run in duplicate.			
Quality Control	BioRad Immunoassay controls 1 and 3 a			
Calculations	N/A			
Interferences	Hemolysis – NSI			
	Icterus – NSI			
	Lipemia – NSI*			
Method Performance	Linear range of detection:			
Specifications	0.5 – 1350 mIU/mL			
	Auto-dilution (1:200) 1050–270.000 mIU/mL			
Dilutions	Do not dilute beyond the auto-dilution by the analyzer, report as > 270,000			

• NSI – No Significant Interference.

• All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.

• Quality Control material- BioRad Unassayed Chemistry controls Level 1 and 2 run daily unless otherwise noted, with each new calibration, with each new reagent bottle loaded, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual.

• Calibration- The system must have a valid calibration in memory before controls or patient samples can be run. Must be Assays must be calibrated following operating requirement specified and also with certain parts replacements or maintenance procedures, as defined in the Instructions for Use manual.

• Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information.

 Refer to LabNet/Health Connect for Reference Ranges and Critical Limits. <u>http://kpnet.kp.org:81/california/scpmg/labnet/</u>

All reagents and controls should be handled as though capable of transmitting infectious diseases. Wear
appropriate personal protective equipment when running patient samples or performing scheduled maintenance.

## Attributes for the Beckman Coulter Access 2 Analyzer

Document History Page								
Change type: New, Major, Minor etc.	Changes Made to SOP - describe	Signature responsible person/date	Med. Director Authorized Reviewed/Date	Lab Ops Dir Authorized Reviewed/Date	Date change Implemented			
New	Consolidated all analytes to an attributes table for the Access 2 analyzer	Yvette Lingat 4/19/2021		Mary Lou Beaumont				