TITLE: VITROS 5600™ INTEGRATED SYSTEM- Reference Ranges/ Critical Values

IDENTIFIER: S-LAB-PC-31112

APPROVED: MEDICAL DIRECTOR
ORIGINAL FORMULATION: 11/5/12

REVISED: 01/2021
REVIEWED: see respective review log

EFFECTIVE:
X Acute Care: **ENC:** √ **GH:** √
LJ: √ **MER:** √
☐ **Home Health:**
☐ **SHAS:**
☐ **SMF:** **SC:** **SCMC:**
CSC:

KEYWORDS:

REFERENCE RANGES/CRITICAL VALUES

****Reference Range not established with NON-Binary Patients.**

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
AGAP	6 - 14		
Albumin	3.5 - 5.0 g/dL		
Alcohol	<10 mg/dL	>300 mg/dL (0.3%) ≤28 days: >13 mg/dl (0.01%)	
Alk Phos	38 –126 Units/L Pediatric (Units/L) 0 - 14 days: male & female 91-256 15 days - <1yr: male & female 131-476 1 - <10 yr: male & female 151-342 10 - <13 yr: male & female 137-424 13 -<15 yr:male 124-474;female 66-252 15 - <17 yrs:male 91-339;female 59-126 17 - <19 yr: male 64-158;female 54-96		
ALT	Male: ≤ 49 Units/L Female: ≤ 34 Units/L		50 u/l 3 days (LIS = 0, 50)
Ammonia	9 - 30 mcmol/L	≤28 days: >100 mcmol/L	50 mcmol/L 3 days (LIS = 1, 50%)
Amylase	30 - 110 Units/L		

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
AST	Male: 17 – 59 Units/L Female: 14 – 36 Units/L Pediatric (Units/L) 0 - 14 days: male 17-184;female 14-184 15 days -<1 yr: male 17-77;female 14-77 1 -<7 yr: male 17-52;female 14-52 7 -<12 yr: male 17-43;female 14-43 12 -<19 yr: male 17-41;female 14-31		50 Units/L 3 days (LIS = 0, 50)
BHB	0.2 – 2.8 mg/dL	>30.0 mg/dL	
BHCG	≤5 mIU/ml: (Negative) Gestational Age: / Level: (mIU/mL) 1-10 wks / 45 - 256,740 11-15 wks / 11,556 - 265,380 16-22 wks / 7,480 - 111,954 23-40 wks / 1,531 - 101,566		
Bilirubin Direct	≤0.3 mg/dL		
BuBc	Neonate: Unconjugated: 0.6 – 10.5 mg/dL Conjugated: 0.0 – 0.6 mg/dL		
BUN	Male:9 – 20 mg/dL Female: 7 - 17 mg/dl		
Calcium	8.4 – 10.2 mg/dL	≤7.0 or ≥12.0 mg/dL	
Cholesterol*	<200 mg/dL Desirable 200-239 mg/dL Borderline High >239 mg/dL High		
CK	Male: 55-170 Units/L Female: 30-135 Units/L		
CK-MB	<4.08ng/mL (Hep Plasma only)		

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
Chloride	98-107 mmol/L		
Creatinine	Male: 0.7–1.3 mg/dL Female: 0.5–1.0 mg/dL	<24 months: ≥1.5 md/dl or >50% increase from previous	<24 months: ≥1.5 md/dl or >50% increase from previous
CO_2	22–30 mmol/L	<10 or > 40 mmol/L	
CRP	<10.0 mg/L		
GGT	Male 15-73 Units/L Female 12-43 Units/L		
Glucose@	≤ 29 days: 40-90 mg/dL >29 days: 70-125 mg/dL	> 28 days : <50 or > 500 mg/dL ≤ 28 days: <40 or > 250 mg/dL	
Glucose (CSF)	40-70 mg/dL		
HDL*	<40 mg/dl Low >59 mg/dL High (Negative Risk Factor)		
K	3.5 – 5.1 mmol/L	>28 days: ≤2.7 or ≥6.0 mmol/L 8-28 days: <3.0 or >6.0 mmol/L ≤ 7 days: <2.8 or > 7.0 mmol/L	0.8 mmol/L 3 days (LIS = 0, 0.8)
Lactate	Venous: 0.7–2.1 mmol/L Arterial: 0.5-0.8 mmol/L	≥ 4.0 mmol/L ≤28 days: >5 mmol/L	
LDH	313 – 618 Units/L		
Lipase	23 – 300 Units/L		
Mg	1.6 – 2.3 mg/dL	≤1.0 or ≥4.0 mg/dL ≤28 days: <1.0 or >3.0	1.0 mg/dL 3 days (LIS = 1, 1.0)
Na	137 – 145 mmol/L	<120 or >160 mmol/L ≤28 days: <125 or >150 mmol/L	10% 3 days (LIS = 1, 10%)
Neonatal Bilirubin Total	(≤28 days) 1.0 –12.0 mg/dL	≤28 days: >15.0 mg/dL	50% 3 days (LIS = 0,50%)

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
Methotrexate Level	Methotrexate Therapeutic Range: Low Dose: 0.50-1.00 umol/L High Dose: 24 hours: <5.00 umol/L 48 hours: < 0.50 umol/L 72 hours: <0.20 umol/L		
Everolimus	None provided. Patient Assessment required		
HIVc	Negative		
	Cut Offs: <1.00 = Non-Reactive ≥1.00 (initial result)=Retest		

@Glucose: If the sample status is Fasting or Unknown, the American Diabetes Association's recommended decision limits will be appended to the result: GLUC2-GLUCF-GLUCI-GLUCD- GLUC3. Samples that are defined as non-fasting will not have the ADA comment appended, but have GLUC1 appended

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
NT-proBNP	<75 years old: ≤125 pg/mL ≥75 years old: ≤450 pg/mL *(attached to inpatient results only):* Optimal Cut-Points (pg/mL) <50 years old: ≤450 50-75 years old: ≤900 > 75 years old: ≤1800 Reference: Junuzzi JL et. al. European Heart Journal. 2006, 27:330-337		
Osmolality, Calculated	280 - 305 mOsm/kg		
Protein/Creatinine Ratio (PCRT)	0 - 200		
Phosphorus	2.5 - 4.5 mg/dL	<1.1 mg/dL	
Protein (CSF)	12–60 mg/dL		
Procalcitonin	0.03-0.08 ng/mL	>2.00 ng/mL	
iPTH	12.4- 76.8 pg/mL		
Total Bilirubin	0.2 –1.3 mg/dL ≤28 days: 1.0 –12.0 mg/dL	≤28 days: >15.0 mg/dL	
Total Protein	6.3 – 8.2 g/dL		
Triglycerides*	<150 mg/dl Normal 150-199 mg/dl Borderline High 200-499 mg/dl High ≥500 mg/dL Very High		
Troponin 1 ES	<0.035 ng/mL (Upper Reference Limit)	≥0.120 ng/mL	
Uric Acid	Male: 3.5 – 8.5 mg/dL Female: 2.5 – 6.2 mg/dL		
TSH	0.465 - 4.68 mIU/L	≤28 days:<0.100 or >10.00 mIU/L	
Maternal HBsAG	Negative Cut Offs: >5.0 = Presumptive Positive <0.90 = Negative ≥0.90 - ≤5.00 Retest		

*Revised National Cholesterol Education Program (NCEP) guidelines for prevention and management of high cholesterol in adults (May, 2001). The relationship between LDL cholesterol and CHD risk is continuous over a broad range of LDL levels. A reduction in LDL levels has been associated with a reduced risk of CHD.
http://www.nhlbi.nih.gov/about/ncep/index.htm

Therapeutic Drug Monitoring:

ANALYTE	THERAPEUTIC RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
Amikacin, Random	No Reference Range	None	
Amikacin, Trough	5-10ug/mL	>10 ug/mL	
Amikacin, Peak	20-25 ug/mL	>35 ug/mL	
Acetaminophen	10-30 mcg/ml	>45 mcg/mL ≤28 days: >30.0 mcg/mL	
Carbamazepine	4.0-12.0 mcg/mL	>12 mcg/mL	
Digoxin	< 1.0 ng/mL	>2.5 ng/mL	
Gentamicin, Random	No Reference Range		
Gentamicin, Trough	0.0-1.9 mcg/mL	>3.0 mcg/mL ≤28 days: >2.5 mcg/mL	
Gentamicin, Peak	4.0-10.0 mcg/mL	>12.0 mcg/mL ≤28 days: >15.0 mcg/mL	
Lithium	0.6-1.2 mmol/L	>1.4 mmol/L	
Phenobarbital	10.0- 40.0 mcg/mL	>60 mcg/mL ≤28 days: >50 mcg/mL	
Phenytoin (Dilantin)	10.0- 20.0 mcg/mL	>30 mcg/mL ≤28 days: >25 mcg/mL	
Salicylate	Negative: <2 mg/dl Therapeutic Range: <20 mg/dl	>30 mg/dl	
Theophylline	10-20 mcg/mL	>25 mcg/mL	
Tobramycin, Random	No Reference Range		
Tobramycin, Trough	0.0 - 1.9 mg/mL	>3.0 mcg/mL ≤28 days:>2.5 mcg/mL	
Tobramycin, Peak	4.0 – 10.0 mcg/mL	>12.0 mcg/mL ≤28 days:>15 mcg/mL	
Valproic Acid	50 -100 mcg/mL	>150 mcg/mL	
Vancomycin, Random	No Reference Range		

Vancomycin, Trough	5 - 20 mcg/mL ≤28 days: 5-10 mcg/mL	>25 mcg/mL ≤28 days: >15 mcg/mL	
Vancomycin, Peak	25 – 40 mcg/mL	>50 mcg/mL ≤28 days: >45 mcg/mL	

Urine Chemistry:

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
FENTANYL	Negative		
UUREA	Reference Interval has not been established for this specimen type		
UCA	24-hr Urine: ≤300 mg/24hr Random: Reference Interval has not been established for this specimen type		
UCREA	24-hr Urine: 0.6 – 2.5 g/24hr Male 24-hr Urine: 0.6 – 1.8 g/24hr Female Random: Reference Interval has not been established for this specimen type		
CRCL	Male: 97 -137 mL/min Female: 88-128 mL/min		
UK	24-hr Urine: 25-125 mmol/24hr (diet dependent) Random: Reference Interval has not been established for this specimen type		
UNA	24-hr Urine: 40-220 mmol/24hr Random: Reference Interval has not been established for this specimen type		
UPRO	24-hr Urine: <150 mg/24hr Random: <12 mg/dl		
URIC	24-hr Urine: 250-750 mg/24hr Random: Reference Interval has not been established for this specimen type		

Body Fluids: (Pleural/thoracentesis; ascites/peritoneal; pericardial; JP drainage only)

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
FLALB	Reference Interval has not been established for this specimen type		
FLAMY	Reference Interval has not been established for this specimen type		
FLCREA	Reference Interval has not been established for this specimen type		

ANALYTE	REFERENCE RANGE	CRITICAL VALUE	DELTA Change/ time interval/ (LIS settings)
FLGLU	Reference Interval has not been established for this specimen type		
FLLD	Reference Interval has not been established for this specimen type		
FLPROT	Reference Interval has not been established for this specimen type		
FLUREA	Reference Interval has not been established for this specimen type		

II. Procedure Notes:

Delta failures are investigated for specimen integrity, patient identification or relevant clinical history before resulting the values, in accordance with procedure *S-LAB-PC_12900 Detection of Patient Data Errors.*

a. Comparison of the same accession number with results in other departments is usually indicated to rule out concerns that the specimen may be compromised for all results on the same blood draw.
b. Possible integrity issues to consider include:
    1. **IV contamination** – Example: may see high glucose with other evidence of dilutional issues such as low or critical electrolyte, Ca results.
    2. **TPN (Total Parental Nutrition)** administration while obtaining the blood draw may give a milky look to the serum/plasma and cause turbidity problems and /or dilutional /lower/ critical results compared to previous results on valid blood draws.
    3. If indicated, correlation of glucose results with POCT glucose values may be helpful in discerning if there is a specimen contamination issue.
c. If the same sample is repeated to verify, append ETC code **CKD** (checked for repeat) as applicable.

Related Documents:

A. S-LAB-PC-31110a Vitros 5600 pH Strip QC & Cutoff Verification Log
B. S-LAB-PC-31110b_ LJ Vitros 5600 Integrated System-Addendum
C. S-LAB-PC-31110c QMS Everolimus on Vitros 5600 Integrated System Torrey Pines Addendum 2
D. S-LAB-PC-31110d Vitros 5600 Integrated System Torrey Pines Addendum
E. S-LAB-PC-31110e_Vitros 5600 integrated System Mercy Addendum
F. S-LAB-PC-31110f_Vitros 5600 Integrated System - User Defined Assays-BHB & Phenobarbital Mercy SD Addendum
G. S-LAB-PC- 31110g_Vitros 5600 - MYSD User Defined Analytes training checklist
H. S-LAB-PC-31110h_Vitros 5600 Integrated System- MYSD Calibration log
I. S-LAB-PC-31110i_Vitros Lot Change-MY SD
J. S-LAB-PC_31110j_Vitros 5600 Integrated System CRP Diluted Result Correction Log
K. S-LAB-PC_31110k_Vitros Daily QC Review Forms & Instructions

L. S-LAB-PC-31111_Vitros 5600 Integrated System -AMR CRR
M. S-LAB-PC-31112_Vitros 5600 Integrated System- Reference Ranges
N. S-LAB-PC-31113_ Vitros 5600 Integrated System- Control Materials
O. S-LAB-PC-15600 Critical Results of Tests
P. S-LAB-PC-30040_Glucose Tolerance Test – Gestational and Non –Gestational
Q. S-LAB-PC-12900 Detection of Patient Data Errors

Policy/Procedure Development		
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