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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Acetaminophen-ACTM]*** | ***[Albumin-ALBm]*** |
| **Methodology/Reaction/Wavelength** | Enzymatic/Rate/340nm | Endpoint BCP/Colorimetry/600nm |
| **Clinical Utility** | Diagnosis of acetaminophen overdose | Diagnosis and treatment for diseases involving the liver and/or kidneys |
|
| **Sample Type** | Serum | Serum |
| Lithium Heparin Plasma | Lithium Heparin Plasma |
|  | Body fluid – pleural and peritoneal fluid (Program sample type as “other”) |
| **Minimum Sample Volume** | 5µL | 5µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hrs | 8 hrs |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | None | All body fluid should be centrifuged |
| **Reagents** | No preparation required | No preparation required |
| Do not mix |
| **Reagent Storage** | 2 ˚C to 8 ˚C | Room Temp |
| **Calculations** | N/A | A/G ratio = Albumin/(TP – Albumin)Globulin = TP - Albumin |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – NSI |
| Icterus - NSI | Icterus - NSI |
| Lipemia – NSI  | Lipemia – NSI  |
| **Method Performance** | Linear range of detection:10 – 300 mcg/mL | Linear range of detection:1.0 to 7.0 g/dL |
| **Specifications** |
|  |
| **Reporting** | Therapeutic range 10 – 30 mcg/mL |

|  |  |
| --- | --- |
| Age | M/F (g/dL) |
| <= 11M | 2.8-4.4 |
| 1-17 Y | 3.1-4.5 |
| >= 18 Y | 3.3-4.8 |

Globulin 1.2 – 4.7 g/dLA/G Ratio: >= 1.0 No established reference range for body fluid albumin |
|  **- Reference Range** |
|   |
| **Reporting** | > 150 mcg/mL | N/A |
| **-Alert Limits** |
| **Dilutions** | Saline – up to maximum of 10 fold dilution | Saline – up to maximum of 2 fold dilution upon physician’s request |
| NSI – No Significant Interference.All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D.  |
| ***DxC 800*** | ***[ALP]*** | ***[ALT]*** |
| **Methodology/Reaction/Wavelength** | Kinetic rate/410nm | Kinetic rate/340nm |
| **Clinical Utility** | Diagnosis and treatment of liver, bone, parathyroid and intestinal diseases | Diagnosis and treatment of liver and heart diseases |
|
| **Sample Type** | Serum | Serum |
| Lithium Heparin Plasma | Lithium Heparin Plasma |
| **Minimum Sample Volume** | 5µL | 23µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hrs | 8 hrs |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | None | None |
| **Reagents** | No preparation required | Transfer all the contents of (A-reagent) bottle into compartment A and mix by gently invert the cartridge.  |
| **Reagent Storage** | 2 ˚C to 8 ˚C | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – will increase result |
| Icterus - NSI | Icterus – NSI |
| Lipemia – NSI  | Lipemia – NSI up to 5 in lipemia index  |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 5-1000 U/L | 5-400 U/L |
|  | ORDAC – 800-1650 U/L | ORDAC – 350 – 2600 U/L |
| **Reporting** |

|  |  |  |
| --- | --- | --- |
| Age | M (U/L) | F (U/L) |
| 0-6D | <=300 | <=300 |
| 7D–2Y | <=270 | <=270 |
| 3Y-5Y | <=415 | <=415 |
| 6Y-15Y | <=500 | <=350 |
| 16Y-19Y | <=225 | <=165 |
| >=20Y | <=125 | <=125 |

 |

|  |  |  |
| --- | --- | --- |
| Age | M | F |
| All age | <=63 U/L | <=54 U/L |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A | N/A |
| **Dilutions** | Saline – up to endpoint upon physician’s request | Saline – up to maximum of 10 fold dilution or endpoint upon physician’s requestResults below detection limit must be rerun with 1:20 dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D.  |
| ***DxC 800*** | ***[Ammonia-AMM]*** | ***[AST]*** |
| **Methodology/Reaction/Wavelength** | Timed endpoint/340nm | Kinetic rate/340nm |
| **Clinical Utility** | Diagnosis of hepatic encephalopathy, hepatic coma and inherited deficiencies in newborns | Diagnosis and treatment of liver and heart diseases |
|
| **Sample Type** | Lithium Heparin Plasma – on ice | Serum |
| Lithium Heparin Plasma |
| **Minimum Sample Volume** | 40µL | 23µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | On-Ice 30 minutes | 8 hrs |
| **Refrigerated** | 30 minutes | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | None | None |
| **Reagents** | No preparation required | Transfer all the contents of (A-reagent) bottle into compartment A and mix by gently invert the cartridge.  |
| **Reagent Storage** | 2 ˚C to 8 ˚C | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – will increase result | Hemolysis – will increase result |
| Icterus – NSI | Icterus – NSI |
| Lipemia – NSI up to 2 in lipemia index | Lipemia – NSI up to 8 in lipemia index  |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 9-1000 µmol/L | 5-400 U/L |
|  |  | ORDAC: 350 – 2600 U/L |
| **Reporting** |

|  |  |
| --- | --- |
| Age | M and F (µmol/L) |
| 0-10D | 100-200 |
| 11D - 2Y | 40-80 |
| > 2Y | 11-35 |

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|  |  |  |
| --- | --- | --- |
| Age | M | F |
| All age | <=34 U/L | <=30 U/L |

 |
|  **- Reference Range** |
|   |
| **Reporting** | N/A | N/A |
| **-Alert Limits** |
| **Dilutions** | Deionized water – up to endpoint upon physician’s request | Saline – up to endpoint upon physician’s request Results below detection limit must be rerun with 1:20 dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D.  |
| ***DxC 800*** | ***[Bun-BUNm]*** | ***[Calcium-CALC]*** |
| **Methodology/Reaction/Wavelength** | Time rated/Conductivity | Endpoint/Indirect ISE |
| **Clinical Utility** | Diagnosis and treatment of renal and metabolic disease | Diagnosis and treatment of parathyroid disease, bone, renal diseases and tetany. |
|
| **Sample Type** | SerumLithium Heparin Plasma | Serum |
| Lithium Heparin Plasma |
| **Minimum Sample Volume** | 10µL | 62µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hrs | 8 hrs |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | None | None |
| **Reagents** | Pour the BUNm wetting agent bottle (100ml) into the 2L bottle. Replace the cap and mix gently by inverting 10 times. The pour contents of the BUN reagent concentrate bottle (200mL) into the 2L bottle. Replace the cap and mix gently by inverting 10 times. Allow reagent to warm to 8-12 hours before using. | ISE electrolyte reference and Buffer reagentNo preparation required |
| **Reagent Storage** | 2 ˚C to 8 ˚C | Room Temp |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – NSI |
| Icterus - NSI | Icterus - NSI |
| Lipemia – NSI | Lipemia – NSI  |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 1.0 – 150 mg/dL | 2.0-20 mg/dL |
|  | ORDAC: 130 -300 mg/dL |  |
| **Reporting** | <=18 mg/dL | 8.5 – 10.7 mg/dL |
|  **- Reference Range** |
|   |
| **Reporting** | N/A | <6.6 mg/dL>12.9 mg/dL |
| **-Alert Limits** |
| **Dilutions** | Saline – up to maximum of 3 fold dilution upon physician’s request | Do not dilute |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |
| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D.  |
| ***DxC 800*** | ***[Carbamazepine-CAR]*** | ***[CK]*** |
| **Methodology/Reaction/Wavelength** | Immuno-Turbidmetry/340nm | Rosalki/340nm |
| **Clinical Utility** | Carbamazepine (Tegretol) is used for treatment of psychomotor, grand mal seizure and trigerminal neuralgia. | Diagnosis and treatment of myocardial infarction and muscle diseases. |
|
| **Sample Type** | SerumLithium Heparin Plasma | Serum |
| Lithium Heparin Plasma |
| **Minimum Sample Volume** | 3µL | 13µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours | 4 days |
| **Refrigerated** | 2 days | 12 hours |
| **Frozen** | Not Established | 3 days |
| **Patient/Sample Preparation** | None | None |
| **Reagents** | No preparation requiredDo not mix | Transfer the entire content of the reagent from compartment C to A, and gently invert the cartridge several times. |
| **Reagent Storage** | 2 ˚C to 8 ˚C | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – will increase CK level |
| Icterus - NSI | Icterus – NSI |
| Lipemia – NSI  | Lipemia – NSI |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 2-15 mcg/dL | 5 - 1200 U/L |
|  |  | ORDAC: 860 – 4100 U/L |
| **Reporting** | Therapeutic range 4 – 12 mcg/mL |

|  |  |  |
| --- | --- | --- |
| Age | M | F |
| All age | 15-190 U/L | 15-170UL |

 |
|  **- Reference Range** |
|   |
| **Reporting** | > 15.0 mcg/mL | N/A |
| **-Alert Limits** |
| **Dilutions** | Saline – up to maximum of 10 fold dilution"SUPPRESSED" due to RXN ERROR should be re-analyze with 1:2 dilution if the error does not resolve by repeating | Saline – up to maximum of 10 fold dilution or until endpoint upon physician’s request |
| NSI – No Significant Interference.All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Chloride-CL]*** | ***[CO2]*** |
| **Methodology/Reaction/Wavelength** | Endpoint/Indirect ISE | Peak rate/Differential rate pH |
| **Clinical Utility** | Diagnosis and treatment of electrolyte and metabolic disorders | Diagnosis and treatment of disorders associated with changes in body acid-base balance |
|
| **Sample Type** | SerumLithium Heparin PlasmaUrine without preservative | Serum |
| Lithium Heparin Plasma |
| **Minimum Sample Volume** | 62µL | 62µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** | Serum/Plasma | Urine |  |
| **Room Temp** | 8 hours | 2 hrs | 8 hours |
| **Refrigerated** | 2 days | 24 hrs | 2 days |
| **Frozen** | Not Established | Not Established | Not Established |
| **Patient/Sample Preparation** | All urine should be centrifuged | Should be capped at all time |
| **Reagents** | ISE electrolyte reference and Buffer reagentNo preparation required | ISE electrolyte reference, Buffer reagent, Acid reagent and CO2 Alkaline buffer.No preparation required |
| **Reagent Storage** | Room Temperature | Room Temperature |
| **Calculations** | Anion gap = Na – (CL + CO2)24hrs urine CL = (UCL x TV)/1000 | Anion gap = Na – (CL + CO2) |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – NSI |
| Icterus - NSI | Icterus - NSI |
| Lipemia – NSI Present of bromide will interfere with CL measurement | Lipemia – NSI  |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | Serum/Plasma 50-200 mEq/L | 5 – 50 mEq/L |
|  | Urine 15 – 300 mEq/L |  |
| **Reporting** | Serum/plasma - 101 – 111 mEq/LNo established reference range for random urine

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| **24 hrs urine chloride** |
| Age | M/F (mEq/24hrs) |
| 0-5 Y | 15-40 |
| 6-11 Y | M: 36-110F: 64-176 |
| 11-15 Y | M:18-74F: 36-173 |
| >15 Y | 110-250 |

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|  |  |
| --- | --- |
| Age | M/F |
| <= 14Y | 18-30 mEq/L |
| > 14Y | 21-31 mEq/L |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A | <11 mEq/L>40 mEq/L |
| **Dilutions** | Do not dilute | Deionized water – up to maximum of 2 fold dilution upon physician’s request |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Creatinine-CREm]*** | ***[CRPH]*** |
| **Methodology/Reaction/Wavelength** | Time rate/colorimetry/520nm/IDMS | Rate Turbidimetry/940nm |
| **Clinical Utility** | Diagnosis and treatment of renal diseases. | Clinical evaluation of infection and inflammation |
|
| **Sample Type** | Serum, Lithium Heparin PlasmaUrine without preservative, Body fluid – pleural and peritoneal fluid (Program sample type as “other”) | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 16.5µL | 20µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** | Serum/Plasma/Body Fluid | Urine |  |
| **Room Temp** | 8 hours | 2 hours | 8 hours |
| **Refrigerated** | 2 days | 24 hours | 3 days |
| **Frozen** | Not Established | Not Established |  Not Recommended |
| **Patient/Sample Preparation** | All body fluid and urine should be centrifuged. Creatinine Clearance - blood obtain within 24 hrs of urine collection | None |
| **Reagents** | Pour 400 mL of Picric acid solution into the 1600 mL alkaline buffer bottle. Replace cap and mix at least 10 times by gentle inversion. | Gently invert the cartridge three times prior to loading |
| **Reagent Storage** | Room Temperature | 2 ˚C to 8 ˚C |
| **Calculations** | Creatinine clearance = [(UC X Vol)/(24X60)]/PC Protein/Creatinine ratio = Urine TP/Urine CreatinineCreatinine 24hrs = (UC x Vol)/100,000eGFR (mL/min/1.73 m2) = 175 x (Scr)-1.154 x (Age)-0.203 x(0.742 if female) x (1.21 if African American) | N/A |
|
| **\*Interferences** | Hemolysis – NSI | Hemolysis – NSIIcterus - NSILipemia – NSI up to 1 on lipemic index. |
| Icterus – NSI up to 7 on the icterus index. Elevated bilirubin will cause a decrease in creatinine |
| Lipemia – NSI  |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | Serum/Plasma 0.3 – 25 mg/dL | 0.2 – 80 mg/L |
|  | Urine 10 – 400 mg/dL | ORDAC: 60 – 380 mg/L |
| **Reporting** |

|  |  |  |
| --- | --- | --- |
|  Serum/Plasma | M | F |
| <= 30 D | <= 0.8  | <= 0.8  |
| 31D - 1Y | <= 0.6 | <= 0.6 |
| 2Y - 19Y | <= 1.0  | <= 1.0 |
| > 19Y | <= 1.3  | <= 1.1 |
| **24 hrs Urine**  |
| All age | 1.0-2.0 gm/spec | 0.8-1.8 gm/spec |
| **Creatinine Clearance** |
| All age | 75 - 125 mL/min |

Reference range for TP/Creat ratio <= 0.19No established reference range for body fluid and random urine creatinine  | < 7.5 mg/L |
|  **- Reference Range** |
|   |
| **Alert Limits** | N/A | N/A |
| **Dilutions** | Saline – (Serum) up to maximum of 2 fold dilution upon physician’s request, (Urine) dilute until endpoint | Do not dilute |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted. Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information.  |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Direct Bilirubin-DBIL]*** | ***[Digoxin-DIGN]*** |
| **Methodology/Reaction/Wavelength** | Diazo/560nm | Turbidimetry/560nm |
| **Clinical Utility** | Diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders | Used for congestive heart failure and certain cardiac arrhythmias |
|
| **Sample Type** | SerumLithium Heparin Plasma | Serum |
| Lithium Heparin Plasma |
| **Minimum Sample Volume** | 10µL | 15µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours | 8 hours |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** |  Not Recommended | Not Established |
| **Patient/Sample Preparation** | None | Digoxin should be measured at least 6 hours after the last dose. Earlier measurements do not reflect tissue concentration and cannot be compared to the stated therapeutic and toxic ranges. |
| **Reagents** | No preparation required | Invert the cartridge several times prior to loading |
| **Reagent Storage** | Room Temperature | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI up to 2 on hemolysis index, hemolysis will decrease direct bilirubin level | Hemolysis – NSIIcterus - NSILipemia – NSI |
| Icterus – NSI  |
| Lipemia – NSI up to 8 on the lipemic index |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 0.1 – 10.0 mg/dL | 0.2 – 4.5 ng/mL |
| **Reporting** | <0.2 mg/dL | Therapeutic range (Indication):Atrial Arrythmia w/o CHF: 0.8-2.0 ng/mLCHF: 0.5-1.1 ng/mLNo Indication: 0.8-2.0 ng/mL  |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A | > 2.0 mg/L |
| **Dilutions** | Do not dilute | Saline – up to maximum of 10 fold dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Ethanol-ETOH]*** | ***[Gentamicin-GEN]*** |
| **Methodology/Reaction/Wavelength** | Diazo/560nm | Turbidimetry/380nm |
| **Clinical Utility** | Diagnosis and treatment of alcohol intoxication and poisoning | Antibiotic used to treat serious gram-negative bacterial infections. |
|
| **Sample Type** | Serum, Plasma fromLithium Heparin/sodium fluoride  | Serum |
| Lithium Heparin Plasma |
| **Minimum Sample Volume** | 10µL | 3µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 2 hours | 8 hours |
| **Refrigerated** | 2 hours | 2 days |
| **Frozen** | Not Established |  Not Recommended |
| **Patient/Sample Preparation** | Non-alcoholic germicidal solution should be used. Not available for medicolegal purpose.Run immediately once uncapped | None |
| **Reagents** | No preparation required | No preparation required. Do not mix |
| **Reagent Storage** | 2 ˚C to 8 ˚C | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – NSIIcterus - NSILipemia – NSIPresent of Sisomicin will increase gentamicin result |
| Icterus – NSI  |
| Lipemia – NSIPresent of n-Propanol, n-Butanol, Isopropanol can increase ETOH |
| **Method Performance** | Linear range of detection: | Linear range of detection: 0.5-12.0 mcg/mL |
| **Specifications** | 5 – 600 mg/dL |
| **Reporting** | <10 mg/dL (None Detected) |

|  |  |
| --- | --- |
| **Test** | **Therapeutic range** |
| Gent Peak |  4–10 mcg/mL |
| Gent Synergy Peak |  <=3 mcg/mL |
| Gent Trough |  <=2 mcg/mL |
| Gent SDDA (0-14Y) | 6-10 mcg/mL |
| Gent SDDA (>14Y) | 8-10 mcg/mL |
| Gent Random |  2-10 mcg/mL |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | > 200 mg/dL |

|  |  |
| --- | --- |
| **Test** | **Critical Value** |
| Gent Peak | 0-14 yrs: >12 mcg/mL>14 yrs: >11 mcg/mL |
| Gent Synergy Peak |  > 6 mcg/mL |
| Gent Trough |  > 2 mcg/mL |
| Gent Random/SDDA | 0-14 yrs: >12 mcg/mL>14 yrs: >11 mcg/mL |

 |
| **Dilutions** | Do not dilute | Saline – up to maximum of 10 fold dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Glucose-GLUm]*** |
| **Methodology/Reaction/Wavelength** | Timed-Peak Rate/Oxygen Consumption |
| **Clinical Utility** | Diagnosis and treatment of carbohydrate metabolism disorders |
|
| **Sample Type** | SerumLithium Heparin Plasma/ Sodium Fluoride PlasmaCSFBody fluid – pleural and peritoneal fluid (Program sample type as “other”) |
|
| **Minimum Sample Volume** | 10µL |
| **Prefer Sample Volume** | 0.3 mL |
| **Specimen Stability** | **Serum/Plasma/Body Fluid** | **CSF** |
| **Room Temp** | 8 hours | 1 hour |
| **Refrigerated** | 2 days | 7 days |
| **Frozen** |  Not Recommended | 6 months |
| **Patient/Sample Preparation** | Patient should be fasting for 12 hours prior to having fasting glucose drawnAll body fluid and CSF should be centrifuged |
| **Reagents** | Prior to use, allow the glucose reagent to equilibrate to room temperature for at least 8 hours. Invert reagent 5 times to mix. |
| **Reagent Storage** | 2 ˚C to 8 ˚C |
| **Calculations** | N/A |
|
| **Interferences** | Hemolysis – NSI, Icterus – NSI, Lipemia – NSI |
|  |
| **Method Performance** | Linear range of detection: 10 – 600 mg/dL ORDAC: 300 – 1200 mg/dL |
| **Specifications** | No established reference range for body fluid glucose |
| **Reporting** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test** | **Age** | **mg/dL** | **Test** | **Age** | **mg/dL** |
| Glucose Fasting | All age | 70-99 | 3 hrs GTT (OB) Fasting - 100 gms | All age | 70-94 |
| Glucose Random | <= 30D | 55-115 | 3 hrs GTT (OB) 1st hr - 100 gms | All age | 70-179 |
| >30D | 70-140 | 3 hrs GTT (OB) 2nd hr - 100 gms | All age | 70-154 |
| 1 hr GTT (OB) - 50 gms | All age | 70-130 | 3 hrs GTT (OB) 3rd hr - 100 gms | All age | 70-139 |
| 2 hrs GTT (OB) Fasting - 75g | All age | 70-91 | 3 hrs GTT - Non-OB 1st hr | All age | 70-189 |
| 2 hrs GTT (OB) 1st hr - 75 gms | All age | 70-179 | 3 hrs GTT - Non-OB 2nd hr | All age | 70-164 |
| 2 hrs GTT (OB) 2nd hr - 75 gms | All age | 70-152 | 3 hrs GTT - Non-OB 3rd hr | All age | 70-144 |
| 2 hrs GTT - Non-OB 2nd hr | All age | 70-200 | Glucose CSF | All age | 50-75 |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | < 45 and >200 mg/dL for neonatal (<=30D)<46 and >484 mg/dL for adult |
| **Dilutions** | Saline – up to maximum of 10 fold dilution. |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |
| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Potassium-K]*** | ***[Lactate-LACT]*** |
| **Methodology/Reaction/Wavelength** | Endpoint/Indirect ISE | Enzymatic/560nm |
| **Clinical Utility** | Diagnosis and treatment of hypokalemia, hyperkalemia, renal failure and Addison’s disease | Diagnosis and treatment of lactic acidosis and sepsis |
|
| **Sample Type** | SerumLithium Heparin PlasmaUrine without preservative | Sodium Fluoride PlasmaCSF |
| **Minimum Sample Volume** | 62µL | 3µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** | Serum/Plasma | Urine | Plasma | CSF |
| **Room Temp** | 8 hours | 2 hrs | 45 mins | 4 hours |
| **Refrigerated** | 2 days | 24 hrs | 2 weeks | 3 days |
| **Frozen** | Not Established | Not Established | 1 month | 6 months |
| **Patient/Sample Preparation** | All urine should be centrifuged | Must be separated from cells within 45 minutes |
| **Reagents** | ISE electrolyte reference and Buffer reagentNo preparation required | No preparation required |
| **Reagent Storage** | Room Temperature | 2 ˚C to 8 ˚C |
| **Calculations** | 24hrs urine K = (UK x TV)/1000 | N/A |
|
| **Interferences** | Hemolysis – NSI up to 2 on the hemolysis indice, hemolysis will increase potassium level | Hemolysis – NSIIcterus - NSILipemia – NSIDetect only L-lactate, does not detectD-lactate |
| Icterus – NSI  |
| Lipemia – NSI |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | Serum/Plasma 1.0 – 15.0 mEq/L | Plasma and CSF: 0.3 – 11.0 mmol/L |
| Urine 2 – 300 mEq/L |  |
| **Reporting** |

|  |  |
| --- | --- |
| Age (Blood) | M/F |
| <=7D | 3.2-5.5 mEq/L |
| 8D – 1Y | 3.5-5.6 mEq/L |
| >=2Y | 3.5-5.0 mEq/L |

No established reference range for random urine and 24 hrs urine sodium for patients 0-4 years old

|  |
| --- |
| **24 hrs urine potassium** |
| Age | M/F (mEq/24hrs) |
| 0-4 Y | N/A |
| 5-14 Y | 17-60 |
| >14 Y | 25-125 |

 |

|  |  |
| --- | --- |
| Age | M/F |
| Plasma (All Age) | 0.5 - 1.9 mmol/L |
| CSF (All Age) | <3.9 mmol/L |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | < 3.0 and >6.4 mEq/L for neonatal (<=30D)< 2.8 and >6.2 mEq/L for adult  | Plasma >1.9 mmol/L |
| **Dilutions** | Do not dilute  | Saline – up to maximum of 10 fold dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[LD]*** | ***[Lipase-LIP]*** |
| **Methodology/Reaction/Wavelength** | Enzymatic rate/340nm | Enzymatic/560nm |
| **Clinical Utility** | Diagnosis and treatment of cancers, liver and cardiac disease. | Diagnosis and treatment of pancreatic disorders |
|
| **Sample Type** | SerumLithium Heparin Plasma Body fluid – pleural and peritoneal fluid (Program sample type as “other”) | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 13µL | 4µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 2 days | 4 hrs |
| **Refrigerated** | 2 days\*\* | 48 hrs |
| **Frozen** | Not Recommended | Not Established |
| **Patient/Sample Preparation** | All body fluid should be centrifuged | None |
| **Reagents** | No preparation required | No preparation required |
| **Reagent Storage** | 2 ˚C to 8 ˚C | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI up to 2 on the hemolysis indice, hemolysis will increase LD level | Hemolysis – NSI up to 4Icterus - NSILipemia – NSI up to 8 |
| Icterus – NSI  |
| Lipemia – NSI |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 5-750 IU/L | 10 – 200 U/L |
| ORDAC: 600 – 2700 IU/L | ORDAC: 180-400 U/L |
| **Reporting** |

|  |  |
| --- | --- |
| Age | M/F |
| <= 1M | <700 IU/L |
| 2M - 16Y | <280 IU/L |
| >=17Y | <181 IU/L |

No established reference range for body fluid LD. |

|  |  |
| --- | --- |
| Age | M/F |
| All Age | <59 U/L |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A | N/A |
| **Dilutions** | Saline – up to maximum of 10 fold dilution | Patient’s serum/plasma with normal lipase result until endpoint upon physician’s request |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information.\*\*Stability based on Mayo Clinic recommendations  |
| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Microprotein M-TP]*** | ***[Magnesium-MG]*** |
| **Methodology/Reaction/Wavelength** | Pyrogallol Red/600nm | Calmagite/520nm |
| **Clinical Utility** | Diagnosis and treatment of conditions with increase CSF protein (meningitis, polyneuritis and tumors) and urine protein (pregnancy and renal disease) | Diagnosis and treatment of uremia, dehydration, diabetic acidosis, Addison’s disease and monitor of increase intake in treatment of preeclampsia |
|
| **Sample Type** | UrineCSF | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 10µL | 3µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 2 hours | 8 hours |
| **Refrigerated** | 7 days | 2 days |
| **Frozen** | 10 days | Not Established |
| **Patient/Sample Preparation** | All CSF and urine should be centrifuged | None |
| **Reagents** | No preparation required | No preparation required |
| **Reagent Storage** | 2 ˚C to 8 ˚C | Room Temperature |
| **Calculations** | M-TP 24hrs = (UTP x Vol)/100Protein/Creatinine ratio = Urine TP/Urine Creatinine | N/A |
|
| **Interferences** | Hemolysis – N/A | Hemolysis – NSI up to 2, hemolysis will increase magnesium levelIcterus - NSILipemia – NSI up to 2, lipemia will increase magnesium level |
| Icterus – N/A |
| Lipemia – N/A |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | CSF: 6 – 300 mg/dL | 0.1 – 7.0 mg/dL |
| Urine: 6 – 150 mg/dL |  |
| **Reporting** |

|  |  |
| --- | --- |
| Age (CSF) | M/F |
| <= 30D | 40-120 mg/dL |
| > 30D | 15-45 mg/dL |
| All Age (Urine) | M/F |
| Random | < 12 mg/dL |
| 24 hours urine | < 150 mg/24 hrs |

Reference range for TP/Creat ratio <= 0.19 | 1.7 – 2.8 mg/dL |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A | < 1.0 and > 4.8 mg/dL  |
| **Dilutions** | Saline – up to maximum of 10 fold dilution (urine) or until endpoint upon physician’s requestSaline - until endpoint upon physician’s request (CSF) | Saline – up to maximum of 10 fold dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |
| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Sodium-NA]*** | ***[Phenobarbital-PHE]*** |
| **Methodology/Reaction/Wavelength** | Endpoint/Indirect ISE | Turbidmetry/340nm |
| **Clinical Utility** | Diagnosis and treatment of aldosteronism, diabetes, adrenal hypertension and dehydration | Used in treatment for status epilepticus, febrile seizures |
|
| **Sample Type** | SerumLithium Heparin PlasmaUrine without preservative | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 62µL | 3µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** | Serum/Plasma | Urine |  |
| **Room Temp** | 8 hours | 2 hrs | 8 hours |
| **Refrigerated** | 2 days | 24 hrs | 2 days |
| **Frozen** | Not Established | Not Established | Not Established |
| **Patient/Sample Preparation** | All urine should be centrifuged | N/A |
| **Reagents** | ISE electrolyte reference and Buffer reagentNo preparation required | No preparation requiredDo not mix |
| **Reagent Storage** | Room Temperature | 2 ˚C to 8 ˚C |
| **Calculations** | Anion gap = Na – (CL + CO2)24hrs urine Na = (UNa x TV)/1000 | N/A |
|
| **Interferences** | Hemolysis – NSI  | Hemolysis – NSI  |
| Icterus – NSI  | Icterus – NSI  |
| Lipemia – NSI | Lipemia – NSI |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | Serum/Plasma 100 – 200 mEq/L | 5.0 – 80.0 mcg/mL |
| Urine 10 – 300 mEq/L |  |
| **Reporting** | Serum/Plasma: 135 – 145 mEq/LNo established reference range for random urine and 24 hrs urine sodium for patients under 0-4 years old

|  |
| --- |
| **24 hrs urine sodium** |
| Age | M/F (mEq/24hrs) |
| 0-4 Y | N/A |
| 5-10 Y | M: 40-115F: 20-69 |
| 11-15 Y | M-:63-177F: 48-168  |
| >15 Y | 40-220 |

 | Therapeutic range 15 – 40 mcg/mL |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | Serum/Plasma: < 120 and > 158 mEq/L  | > 50 mcg/mL |
| **Dilutions** | Do not dilute | Saline – up to maximum of 10 fold dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |
| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Phosphorus-PHOSm]*** | ***[Phenytoin-PHY]*** |
| **Methodology/Reaction/Wavelength** | Time rate/Colorimetry/365nm | Turbidmetry/340nm |
| **Clinical Utility** | Diagnosis and treatment of parathyroid gland and kidney disease | Used in treatment of grand mal and cortical focal seizures |
|
| **Sample Type** | SerumLithium Heparin Plasma | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 8µL | 3µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours | 8 hours |
| **Refrigerated** | 2 days | 1 day |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | N/A | N/A |
| **Reagents** | Pour 200 mL of molybdate solution into the 1800 mL of diluentReplace cap and mix at least 10 times by gentle inversion | No preparation requiredDo not mix |
| **Reagent Storage** | Room Temperature | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI up to 2, hemolysis will increase phosphorus level | Hemolysis – NSI  |
| Icterus – NSI  | Icterus – NSI  |
| Lipemia – NSI | Lipemia – NSI |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 1.0 – 12.0 mg/dL | 2.5 – 40.0 mcg/mL |
|  |  |
| **Reporting** |

|  |  |
| --- | --- |
| Age  | M/F |
| <= 10D | 4.5 – 8.0 mg/dL |
| 11D – 2Y | 4.5 – 6.7 mg/dL |
| 3Y – 12 Y | 4.5 – 5.5 mg/dL |
| >= 13Y | 2.7 – 4.5 mg/dL |

 | Therapeutic range 10 – 20 mcg/mL |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A  | > 25 mcg/mL |
| **Dilutions** | Saline – up to maximum of 3 fold dilution upon physician’s request | Saline – up to maximum of 10 fold dilution |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Salicylate-SALY]*** | ***[Total Bilirubin-TBIL]*** |
| **Methodology/Reaction/Wavelength** | Enzymatic/340nm | Jendrassik-Grof/520nm |
| **Clinical Utility** | Used as analgesic, antipyretic and anti-inflammatory | Diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders |
|
| **Sample Type** | SerumLithium Heparin Plasma | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 4µL | 8µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours | 8 hours |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | N/A | Bilirubin is photosensitive. Protect samples from light. If delay is longer than 8 hrs |
| **Reagents** | No preparation required | Transfer 200 µL from compartment C to compartment B. Gently invert the cartridge several time |
| **Reagent Storage** | 2 ˚C to 8 ˚C | Room Temperature |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI up to 6 | Hemolysis – NSI up to 2, hemolysis will increase bilirubin result |
| Icterus – NSI up to 7 | Icterus – NSI  |
| Lipemia – NSI up to 5 | Lipemia – NSI up to 5, lipemia will decrease bilirubin result |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 4 – 100 mg/dL  | 0.1 – 30.0 mg/dL |
| **Reporting** | Therapeutic range 0-13 Yrs old: < 15.0 mg/dL>13 Yrs old: 15 – 30 mg/dL |

|  |  |
| --- | --- |
| 0 – 23H | <= 6.0 mg/dL |
| 1-2 Day | <= 7.0 mg/dL |
| 3-5 Days | <= 12.0 mg/dL |
| >=6 Days | <= 1.0 mg/dL |

 |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | 0-13 Yrs old: > 15 mg/dL>13 Yrs old: > 35 mg/dL  |

|  |  |
| --- | --- |
| 0 – 23H | > 8.0 mg/dL |
| 1 Day | > 11.4 mg/dL |
| 2 Days | > 13.6 mg/dL |
| 3 Days | > 14.5 mg/dL |
| 4 Days | > 15.0 mg/dL |
| 5-29 Days | > 18.0 mg/dL |

 |
| **Dilutions** | Saline – up to maximum of 10 fold dilution | Patient’s serum/plasma with bilirubin <1.0, up to maximum of 2 fold dilution  |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Theophyline-THE]*** | ***[Total Protein-TPm]*** |
| **Methodology/Reaction/Wavelength** | Turbidmetry/340nm | Timed rate/colorimetry/545nm |
| **Clinical Utility** | Used in treatment of bronchial asthma | Diagnosis and treatment of diseases involving liver, kidney and bone marrow, as well as other metabolic and nutritional disorders |
|
| **Sample Type** | SerumLithium Heparin Plasma | SerumLithium Heparin PlasmaBody fluid – pleural and peritoneal fluid (Program sample type as “other”) |
| **Minimum Sample Volume** | 3µL | 8µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours | 8 hours |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | N/A | All body fluid should be centrifuged |
| **Reagents** | No preparation requiredDo not mix | No preparation required |
| **Reagent Storage** | 2 ˚C to 8 ˚C | Room Temperature |
| **Calculations** | N/A | A/G ratio = Albumin/(TP – Albumin)Globulin = TP - Albumin |
|
| **Interferences** | Hemolysis – NSI | Hemolysis – NSI  |
| Icterus – NSI  | Icterus – NSI  |
| Lipemia – NSI up to 8 on the lipemia index | Lipemia – NSI up to 2, lipemia will decrease total protein result |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 2.0 – 40.0 mcg/mL | 3.0 – 12.0 g/dL |
|  |  |
| **Reporting** | Therapeutic range 5 – 15 mcg/mL |

|  |  |
| --- | --- |
| <= 1Y | 4.3 - 6.9 g/dL |
| 2 - 3Y | 5.2 - 7.4 g/dL |
| 4 - 6Y | 5.6 - 7.7 g/dL |
| 7 - 10Y | 6.5 - 8.3 g/dL |
| >= 11Y | 6.1 - 8.0 g/dL |

Globulin 1.2 – 4.7 g/dLA/G Ratio: >= 1.0 No established reference range for body fluid total protein |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | > 20 mcg/mL  | N/A |
| **Dilutions** | Saline – up to maximum of 10 fold dilution | Saline – up to maximum of 2 fold dilution upon physician’s request |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |
| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Uric Acid-URIC]*** | ***[Valproic Acid-VPA]*** |
| **Methodology/Reaction/Wavelength** | Enzymatic Trinder/520nm | Turbidmetry/520nm |
| **Clinical Utility** | Diagnosis and treatment of renal and metabolic disorders including renal failure, gout, leukemia, psoriasis and starvation | Used in treatment of petite mal, generalized tonic-clonic and myoclonic seizures |
|
| **Sample Type** | SerumLithium Heparin Plasma | SerumLithium Heparin Plasma |
| **Minimum Sample Volume** | 12µL | 3µL |
| **Prefer Sample Volume** | 0.3 mL | 0.3 mL |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours | 8 hours |
| **Refrigerated** | 2 days | 2 days |
| **Frozen** | Not Established | Not Established |
| **Patient/Sample Preparation** | N/A | N/A |
| **Reagents** | No preparation required | Gently invert the cartridge three times prior to loading |
| **Reagent Storage** | 2 ˚C to 8 ˚C | 2 ˚C to 8 ˚C |
| **Calculations** | N/A | N/A |
|
| **Interferences** | Hemolysis – NSI up to 2, hemolysis will increase uric acid | Hemolysis – NSI  |
| Icterus – NSI up to 4, bilirubin will increase uric acid | Icterus – NSI  |
| Lipemia – NSI up to 8 on the lipemia index\*N-Acetyl Cysteine (NAC) used in treatment of acetaminophen overdose will falsely decrease uric acid result | Lipemia – NSI up to 5 on the lipemia index\* |
| **Method Performance** | Linear range of detection: | Linear range of detection: |
| **Specifications** | 0.5 – 12.0 mg/dL | 10.0 – 150.0 mcg/mL |
| ORDAC: 9.0 – 21.0 mg/dL |  |
| **Reporting** |

|  |  |
| --- | --- |
| <= 10Y | 1.9 - 5.4 mg/dL |
| 11 - 18Y | 3.5 - 7.3 mg/dL |
| >= 19Y (M) | 3.4 - 7.2 mg/dL |
| >= 19Y (F) | 2.7 - 6.6 mg/dL |

 | Therapeutic range 50 – 150 mcg/mL |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | N/A  | > 170 mcg/mL |
| **Dilutions** | Saline – up endpoint upon physician’s request | Saline – up to maximum of 10 fold dilution"SUPPRESSED" due to RXN ERROR should be re-analyze with 1:2 dilution if the error does not resolve by repeating |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

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| **Attributes for the DxC 800 Analyzer**  Effective Date: 06/06/16 Area Lab Manager: Cindy Schwartz, CLS |
| Document #/version # 04-008v.1 Laboratory Director: Jana Pindur M.D. |
| ***DxC 800*** | ***[Vancomycin-VANC]*** |  |
| **Methodology/Reaction/Wavelength** | Turbidmetry /340nm |  |
| **Clinical Utility** | Used in treatment of infection due to beta-lactam or methronidazole-resistant gram positive cocci and bacilli. |  |
|
| **Sample Type** | SerumLithium Heparin Plasma |  |
| **Minimum Sample Volume** | 3µL |  |
| **Prefer Sample Volume** | 0.3 mL |  |
| **Specimen Stability** |  |  |
| **Room Temp** | 8 hours |  |
| **Refrigerated** | 2 days |  |
| **Frozen** | Not Established |  |
| **Patient/Sample Preparation** | N/A |  |
| **Reagents** | Gently invert the cartridge three times prior to loading |  |
| **Reagent Storage** | 2 ˚C to 8 ˚C |  |
| **Calculations** | N/A |  |
|
| **Interferences** | Hemolysis – NSI  |  |
| Icterus – NSI  |  |
| Lipemia – NSI |  |
| **Method Performance** | Linear range of detection: |  |
| **Specifications** | 3.5 – 40.0 mcg/mL |  |
| ORDAC: 30 – 60.0 mcg/mL |  |
| **Reporting** |

|  |  |
| --- | --- |
| Trough | 10 – 20 mcg/mL |
| Random | 10 – 40 mcg/mL |

 |  |
|  **- Reference Range** |
|   |
| **Reporting****-Alert Limits** | > 50.0 mcg/mL |  |
| **Dilutions** | Saline – up to maximum of 10 fold dilution |  |
| NSI – No Significant Interference. All serum/plasma samples should be centrifuge within 2 hours from collection unless otherwise noted.  |
| Refer to the Beckman chemistry information sheet, operator tips and operating manual for more detailed information. |

**Document History Page**

**Effective Date:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Change type: New, Major, Minor etc.** | **Changes Made to SOP - describe** | **Signature responsible person/date** | **Med. Director****Authorized Reviewed/Date** | **Operational Director****Authorized****Reviewed/Date** | **Date change Implemented** |
| Major | New  | Cindy Schwartz6/8/16 |  |  |  |
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