Reference Intervals

The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.(6)

Reference Intervals

Intervals	Sample Type	Conventional Units	
Literature	Serum or Plasma	3.4 – 4.8 g/dL	
SYNCHRON	Serum or Plasma	3.5 – 4.8 g/dL	
UCDMC	Serum or Plasma	14 – 18 yrs	3.2 – 4.5 g/dL
	Serum or Plasma	18 – 60 yrs	3.4 – 4.8 g/dL

Refer to References (7,8,9) for guidelines on establishing laboratory-specific reference intervals.

Pediatric reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid albumin result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (g/dL)
Ammonium Heparin	14 Units/mL	NSI[a]
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI

[a] NSI = No Significant Interference (within ±4.0 mg/dL or 4%).

The following anticoagulants were found to be incompatible with this method:

Incompatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (g/dL[a])
Potassium Oxalate/Sodium Fluoride	2.0/2.5 mg/mL	-2.3

[a] Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

Limitations

Bromcresol purple dye is specific for human albumin. Bovine-based albumin controls may recover differently.

Quality Control Material

Control	Storage
MAS ChemTrak 1	2°C to 8°C*
MAS ChemTrak 3	2°C to 8°C*

*Controls are received frozen and stored at –15°C to –25°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

Testing Procedure

1. If necessary, load the reagent onto the system.
2. Program samples and controls for analysis.
3. After loading samples and controls onto the system, follow the protocols for system operation.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

For dilutions programmed in Remisol: the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

Reporting Results

Equivalency between the SYNCHRON LX and UniCel DxC 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

Reference Intervals

The following reference intervals were taken from literature.(6) UCDMC adult reference interval was determined from a normal study.

Reference Intervals

Intervals	Sample Type	Conventional Units
Literature	Serum or Plasma	28 - 100 U/L
UCDMC	Serum or Plasma	33 - 130 U/L

Refer to References (7, 8, 9) for guidelines on establishing laboratory-specific reference intervals
Conversion factor from conventional units(U/L) to S.I. Units (µkat/L) is 0.01667

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid amylase result:

This test was developed and its performance characteristics determined by UCDMC, Automated Chemistry Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Critical Values

None

LDL/HDL ratio: this can be calculated as Friedewald LDL - HDL when the triglyceride level is ≤ 400 mg/dL. When a Direct LDL assay is performed, the LDL-D value is used in the ratio instead of the calculated LDL.

Non-HDL Cholesterol: calculated result (to conform with the latest NCEP ATPIII guidelines)

Non-HDL Cholesterol = [Total Cholesterol – HDL Cholesterol]

The clinician will be able to order a Lipid Panel that reflexes to a direct LDL if the LDL calculation is not performed. The direct LDL will only be performed on samples if the fasting triglyceride is > 400 mg/dL and ≤ 1000 mg/dL, or for non-fasting samples if the triglyceride is > 150 mg/dL and ≤ 1000 mg/dL.

Reporting Results

Equivalency between the SYNCHRON LX and UniCel DxC 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

Reference Intervals

The National Cholesterol Education Program has published reference cholesterol values for cardiovascular risk to be:

Reference Intervals

Less than 200 mg/dL	low risk
201 - 239 mg/dL	borderline risk
240 mg/dL and greater	high risk

Refer to Reference (7) for additional reference intervals according to age and sex.

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid cholesterol result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Refer to References (8,9,10) for guidelines on establishing laboratory-specific reference intervals.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Acceptable Anticoagulants[a]

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias
Ammonium Heparin	29 Units/mL	NSI[b]
Lithium Heparin	29 Units/mL	NSI
Sodium Heparin	29 Units/mL	NSI

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.
[b] NSI = No Significant Interference (within ±10.0 mg/dL or 6%).

Reference interval for a spot or random urine sample has not been established.

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid creatinine result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

eGFR Reference Interval:

> 60 mL/min./1.73 square meters

The NKDEP recommends reporting eGFR values **greater than or equal to 60 mL/min/1.73 m^2** simply as "≥60 mL/min/1.73 m^2," not as an exact number.

For values **below 60 mL/min/1.73 m^2**, the report should give the numerical estimate rounded to a whole number (e.g., "32 mL/min/1.73 m^2").

The equation has been most extensively evaluated in people with chronic kidney disease and reduced GFR and is less accurate for persons with normal or mildly impaired kidney function.

Quantification of eGFR values of 60 mL/min/1.73 m^2 and below have more clinical implications for classification of kidney function than values above this level.

Note: The estimated GFR result assumes a steady-state and is most accurate for GFRs <60mL/min./1.73m^2. The eGFR is not reliable in certain groups, including severely ill patients. Also, patients > 59 years of age can have a mildly reduced GFR due to aging. The MDRD equations used to estimate GFR have been validated only in Caucasians and African-Americans 18 - 70 years of age. The equations have not been validated in other population groups, including pregnant women, transplant recipients, medically unstable patients including those with acute renal failure, or in persons with extremes of body size, muscle mass, or nutritional status. Application of the MDRD calculation in these cases may lead to errors in GFR estimation.

For more information, refer to the NKDEP website: http://www.nkdep.nih.gov

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)[a]
Ammonium Heparin	14 Units/mL	NSI
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI
Potassium Oxalate/ Sodium Fluoride	2.0 / 2.5 mg/mL	NSI

[a] NSI = No Significant Interference (within ± 0.2 mg/dL or 6%).

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid glucose result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only

Critical Values

Glucose results **≤ 40** mg/dL and **≥ 300** mg/dL for newborns (**0 days to 2 days old)** are considered critical values and should be called immediately to the attending physician or charge nurse.

Glucose results **≤ 50** mg/dL and **≥ 300** mg/dL for neonates to teens (**> 2 days to 17 yrs old**) are considered critical values and should be called immediately to the attending physician or charge nurse.

Glucose results **≤ 50** mg/dL and **≥ 500** mg/dL for adults (**≥ 18 yrs old**) are considered critical values and should be called immediately to the attending physician or charge nurse.

Immediately report all critical low values. Glucose results ≤ 50 mg/dL must be repeated for confirmation, and will be sorted for repeat by Remisol. A comment stating "GLUCOSE <=50 mg/dL. IF INPT - CALL CV IMMEDIATELY, THEN REPEAT. IF OUTPT - REPEAT PRIOR TO CALLING CV. RELOAD FRONT-LOADED SAMPLES FOR RECHECK" will appear in the Remisol Messages window.

Front-loaded samples must be manually reloaded. Samples on the line will automatically rerun.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	NSI[a]
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	NSI

[a] NSI = No Significant Interference (within ±4.0 mg/dL or 4%).

Limitations

If sodium fluoride is used as a preservative, a decrease of 9 mg/dL is seen during the first 2 hours.(7) 2.If CSF samples are cloudy or turbid or if CSF samples are visibly contaminated with blood, it is recommended that they be centrifuged before transfer to a sample cup.

Freshly prepared D-glucose solutions or commercial controls spiked with D-glucose must be allowed to mutarotate before analysis for accurate results.

Oxygenated samples will cause low results.

If sodium fluoride is used as a preservative, a decrease of 9 mg/dL is seen during the first 2 hours.

Reference Intervals

Intervals	Sample Type	Conventional Units
Literature	Serum or Plasma	100 - 190 IU/L
SYNCHRON	Serum or Plasma	98 - 192 IU/L
UCDMC	Serum or Plasma	100 - 190 IU/L

Refer to References (6, 7, 8) for guidelines on establishing laboratory-specific reference intervals.

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid LDH result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (IU/L)
Ammonium Heparin	14 Units/mL	NSI[a]
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI

[a] NSI = No Significant Interference (within ±6.0 IU/L or 7%).

The following anticoagulants were found to be incompatible with this method

Incompatible Anticoagulants:

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (IU/L)[a]
EDTA	1.5 mg/mL	- 27
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	- 140

[a] Bias is based on worst case instead of average.
Plus (+) or minus (-) signs in this column signify positive or negative interference.

Limitations

None identified.

Pediatric reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid total biliurubin result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Critical Values

Total bilirubin result **≥18.0 mg/dL** is considered a critical value for all newborns < 30 days old and should be called immediately to the attending physician or charge nurse.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Acceptable Anticoagulants[a]

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Sodium Heparin	29 Units/mL	NSI[b]
Ammonium Heparin	29 Units/mL	NSI
Lithium Heparin	29 Units/mL	NSI

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has be established by Deming regression analysis to SYNCHRON CX Systems.

[b] NSI = No Significant Interference (within ± 0.3 mg/dL or 6%).

The following anticoagulants were found to be compatible with this method.

Incompatable Anticoagulants[a]

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Sodium Citrate	1.7 mg/dL	≤ 0.8
Potassium Oxalate/ Sodium Fluoride	4.0/5.0 mg/dL	≤ -0.4

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has be established by Deming regression analysis to SYNCHRON CX Systems.

[b] Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

Limitations

None identified.

Non-HDL Cholesterol: calculated result (to conform with the latest NCEP ATPIII guidelines)

Non-HDL Cholesterol = [Total Cholesterol – HDL Cholesterol]

The clinician will be able to order a Lipid Panel that reflexes to a direct LDL if the LDL calculation is not performed. The direct LDL will only be performed on samples if the fasting tryiglyceride is > 400 mg/dL and ≤ 1000 mg/dL, or for non-fasting samples if the triglyceride is > 150 mg/dL and ≤ 1000 mg/dL.

Reporting Results

Equivalency between the SYNCHRON LX and UniCel DxC 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

Reference Intervals

The Adult Treatment Panel of the Center for Disease Control (CDC) recommends triglyceride values for cardiovascular risk to be:(6,7)

Reference Intervals

Cardiovascular Risk	Conventional Units
Normal	Less than 150 mg/dL
Borderline high	150 - 199 mg/dL
High	200 - 500 mg/dL
Very high	Greater than 500 mg/dL

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid triglyceride result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Refer to Reference (8) for additional reference intervals according to age and sex.

Refer to References (9,10,11) for guidelines on establishing laboratory-specific reference intervals.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Acceptable Anticoagulants[a]

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias
Ammonium Heparin	29 Units/mL	NSI[b]
Lithium Heparin	29 Units/mL	NSI
Sodium Heparin	29 Units/mL	NSI

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.
[b] NSI = No Significant Interference (within ±10.0 mg/dL or 6%).

Reference Intervals

The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.(5)

Reference Intervals

Intervals	Sample Type	Conventional Units
Literature	Serum (Adult Ambulatory)	6.4 – 8.3 g/dL
	Serum (Adult Recumbent)	6.0 – 7.8 g/dL
SYNCHRON	Serum	6.1 – 7.9 g/dL
UCDMC	Serum or Plasma	6.3 – 8.3 g/dL

Refer to References (3,6,7) for guidelines on establishing laboratory-specific reference intervals.

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid protein result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (g/dL)
Ammonium Heparin	14 Units/mL	NSI[a]
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI

[a] NSI = No Significant Interference (within ± 0.4 g/dL or 4%).

The following anticoagulants were found to be incompatible with this method:

Incompatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (g/dL)[a]
Potassium Oxalate/Sodium Fluoride	2.0/2.5 mg/mL	-1.3

[a] Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.