TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	5/2/2013
Department:	Core	**Due Date:**	5/15/2013
		Implementation:	**5/15/2013**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Bilirubin by Dimension® Xpand Chemistry Analyzer GEC.C33.000 **Xpand Limits Chart AG.F143.004**
Description of change(s):
New SOP for upcoming implementation of TBI and DBI reagents (replaces SOP for reagents TBIL / DBIL). Changes include: • update to TBI / DBI calibrator • new limits for CRR and AMR This SOP will be implemented on May 15, 2013 Note: the change to reagent ALTI will also occur on 5/15.

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 000)

Technical SOP

Title	**Bilirubin by Dimension® Xpand Chemistry Analyzer**
Prepared by	Ashkan Chini Date: 12/3/2012
Owner	Robert SanLuis Date: 12/3/2012

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Annual Review		
Print Name	**Signature**	**Date**

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Bilirubin, Direct	Dimension® Xpand Chemistry Analyzer	DBIL
Bilirubin, Indirect		(Calculated value)
Bilirubin, Total		TBIL
Bilirubin, Neonatal		TBILN, DBILN
Bilirubin, Cord		CBIL

Synonyms/Abbreviations
Bili, Tbi, Dbi, NBi, CBi Bilirubin Direct and Total are included in Batteries/Packages: COMP, LIVP Bilirubin Neonatal is included in Batteries/Packages: NBIL

Department
Chemistry

2. ANALYTICAL PRINCIPLE

Total Bilirubin

Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. Bilirubin (unconjugated) in the sample is solubilized by dilution in a mixture of caffeine/benzoate/acetate/EDTA. Upon addition of the diazotized sulfanilic acid, the solubilized bilirubin including conjugated bilirubins (mono and diglucoronides) and the delta form (biliprotein-bilirubin covalently bound to albumin) is converted to diazo-bilirubin, a red chromophore representing the total bilirubin which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique. A sample blank correction is used.

Solubilized bilirubin + Diazotized sulfanilic acid ----------> Red chromophore
(absorbs at 540 nm)

Direct Bilirubin

Diazotized sulfanilic acid is formed by combining sodium nitrite and sulfanilic acid at low pH. The sample is diluted in 0.5M HCl. A sample blank reading is taken to eliminate interference from non-bilirubin pigments. Upon addition of the diazotized sulfanilic acid, the conjugated bilirubin is converted to diazo-bilirubin, a red chromophore which absorbs at 540 nm and is measured using a bichromatic (540, 700 nm) endpoint technique.

Conjugated bilirubin + Diazotized sulfanilic acid ----------> Red chromophore
(absorbs at 540 nm)

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Heparin) Serum, Cord Blood, Plasma (EDTA)
Collection Container	Plasma: Green top tube Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL

Criteria	
Transport Container and Temperature	Collection container or Plastic vial at room temperature, protect from light.
Storage Requirements	Protect from light
Stability Requirements	Room Temperature: 8 hours
	Refrigerated: 7 days
	Frozen: 6 months
Timing Considerations	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Bilirubin is photosensitive. Protect sample from daylight and fluorescent light to avoid degradation. Allow Red Top or SST to clot completely prior to centrifugation.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Total Bilirubin	Siemens, Flex® reagent cartridge, Cat. No. DF167
Direct Bilirubin	Siemens, Flex® reagent cartridge, Cat. No. DF125

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	**Total Bilirubin**
Container	Reagent cartridge

Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1, 4 - 6 have been entered by the instrument, they are stable for 5 days. • Once well 3 has been entered by the instrument, it is stable for 3 days. • Diazotized sulfanilic acid in well 2 prepared by the automatic addition of sodium nitrite from well 3 is stable for 15 days.
Preparation	All reagents are liquid and ready to use.

Reagent	**Direct Bilirubin**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 4 have been entered by the instrument, they are stable for 2 days. • Once wells 5 - 8 have been entered by the instrument, they are stable for 30 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
TBI/DBI Calibrator	Siemens Dimension®, Cat. No. DC167

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	TBI/DBI Calibrator
Preparation	• Remove vials from the refrigerator and proceed directly to the next step. • Remove stopper and volumetrically add 1.0 ± 0.01 mL of reagent grade water. • Replace stopper, and let stand for 5 minutes. Do not invert the vials.

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	• Swirl vials gently for 30 seconds, then gently invert 10 times. • Let vials stand on bench top for 10 minutes, then invert gently 10 times. • Let vials stand on bench top for 15 minutes, then invert gently 10 times and swirl gently. • Use immediately or refrigerate at 2-8° C for future use.
Storage/Stability	• Store at 2-8° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **Opened Calibrator:** Assigned values are stable for 24 hours after reconstitution when vials are stoppered and stored at 2-8° C. Product exposure to light may cause significant decrease in bilirubin concentration.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	**TBI/DBI Calibrator**
Assay Range	Total Bilirubin: 0.1 – 25.0 mg/dL Direct Bilirubin: 0.1 – 16.0 mg/dL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	3 levels, n = 3

5.4 Calibration Procedure

1. From Operating Menu press F5:Process Control press F1: Calibration Enter Password press F2: SETUP and RUN
2. Select the test method to be calibrated - if lot number is incorrect Press F1: Other Lot
3. Enter all information on screen
4. Press F8: QC yes/no to change to yes
5. Press F4: Assign cups If additional methods need to be calibrated, select the method.
6. Press F7: Load/run

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7. Load cups into assigned position
8. Press F4: RUN

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat. No 691 and 692
Liquichek™ Pediatric Control Level 2	Bio-Rad Laboratories Cat. No. 355

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	**Liquichek Unassayed Chemistry Controls, Level 1 and 2**
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	Once the control is thawed, bilirubin will be stable for 6 days at 2-8°C. Unthawed controls are stable until the expiration date at -20 to -70°C.

Control	**Liquichek Pediatric Control, Level 2**
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.

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Storage/Stability	Once the control is thawed, bilirubin will be stable for 14 days at 2-8°C. Unthawed controls are stable until the expiration date at -20 to -70°C.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Dimension Xpand® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension X-pand® Quick Reference Guide.

6.4 Tolerance Limits

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

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6.5 Review Patient Data

Technologist must review each result print-out for error messages. Refer to the Dimension® system manual "Error messages" section for troubleshooting. Check

for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups
- Calibrated pipettes and disposable tips
- Reagent grade water

8. PROCEDURE

TBI Flex® reagent cartridge Cat. No. DF167 and DBI Flex® reagent cartridge Cat. No. DF125 is required to perform this test.

Bilirubin is performed on the Dimension Xpand® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	**Instrument Set-Up Protocol**
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® Xpand procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® Xpand system. For details of the automated parameters, see below under "Test conditions."

8.2	**Specimen/Reagent Preparation**
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® Xpand segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® Xpand procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	**Specimen Testing**
1.	For QC placement and frequency, refer to the Dimension® Xpand QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Xpand Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension® Xpand system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Repeat critical values and document according to Critical Values procedure. Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

Test Conditions		
	TBI	**DBI**
Sample Volume:	10 µL	10 µL
Reagent 1 Volume:	250 µL	25 µL
Reagent 2 Volume:	47 µL	50 µL
Test Temperature:	37° C	
Wavelength:	540 and 700 nm	
Type of measurement:	Bichromatic endpoint	

9. CALCULATIONS

The instrument automatically calculates the concentration of Bilirubin in mg/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results up to one decimal point.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

Total Bilirubin: 0.1 – 125.0 mg/dL

Direct Bilirubin: 0.1 – 80.0 mg/dL

10.5 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

Total Bilirubin:

IF the result is …	**THEN…**
< 0.1 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.1 mg/dL

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≥ 25.0 mg/dL	**On Board Automated Dilution:** Results ≥ 25.0 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 2. No multiplication is necessary.
> 50.0 mg/dL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 5 **Diluent:** Water Enter dilution factor as a whole number on the "Enter Sample Data" screen. Reassay. Resulting readout is corrected for dilution.
> 125.0 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 125.0 mg/dL-REP" Bring to the attention of your supervisor prior to releasing result.

Direct Bilirubin:

IF the result is …	**THEN…**
< 0.1 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.1 mg/dL
≥ 16.0 mg/dL	**On Board Automated Dilution:** Results ≥ 16.00 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 1.9. No multiplication is necessary.
> 30.4 mg/dL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 5 **Diluent:** Water Enter dilution factor as a whole number on the "Enter Sample Data" screen. Reassay. Resulting readout is corrected for dilution.
> 80.0 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 80.0 mg/dL-REP" Bring to the attention of your supervisor prior to releasing result.

Message	**Code**
Verified by repeat analysis	Append –REP to the result.

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11. EXPECTED VALUES

11.1 Reference Ranges

Total Bilirubin:

Age	Male/Female
Adult (> 17 years):	< 1.0 mg/dL
Pediatric:	
0 – 24 hours	< 5.1
1 – 2 days	< 7.2
3 days – 30 days	< 10.3
1 month – 17 years	< 0.8

Direct Bilirubin, all ages 0.0 – 0.2 mg/dL

11.2 Critical Values

Total Bilirubin, all ages ≥ 18.0 mg/dL

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Measurements of bilirubin are used in the diagnosis and treatment of liver, hemolytic hematological and metabolic disorders, including hepatitis and gall bladder disease. There are at least four distinct bilirubin species that make up the total bilirubin in serum. The direct reacting species are mono-and diconjugated bilirubin (β- and γ-bilirubin) and the delta fraction (δ-bilirubin), which is tightly bound to albumin. Unconjugated bilirubin (α-bilirubin) is water-insoluble and reacts only after addition of an accelerator such as caffeine.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Xpand Operator's Guide.

A system malfunction may exist if the following 5-test precision is observed:

TBIL Concentration	**Acceptable S.D. Maximum**
1.1 mg/dL	> 0.03 mg/dL
18.8 mg/dL	> 0.56 mg/dL
DBIL Concentration	**Acceptable S.D. Maximum**
0.6 mg/dL	> 0.06 mg/dL
16.0 mg/dL	> 0.34 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Total Bilirubin: 0.1 – 25.0 mg/dL
Direct Bilirubin: 0.1 – 16.0 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
TBIL, Serum Pool	18.2	0.27 (1.5)	0.47 (2.6)
TBIL, MAS bilirubin 3	6.3	0.1 (1.5)	0.2 (2.4)
DBIL, Serum Pool 1	12.2	0.04 (0.4)	0.11 (0.9)
DBIL, Serum Pool 2	21.5	0.08 (0.4)	0.16 (0.8)

14.3 Interfering Substances

HIL Interference:

The TBI and DBI method was evaluated for interference according to CLSI/NCCLS EP7-A2. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

Substance tested	Substance Concentration	TBIL mg/dL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	1.1, 24.8	<10
Lipemia Intralipid®	200 mg/dL 600 mg/dL	1.1	18, <10

Substance tested	Substance Concentration	DBIL mg/dL	Bias %
Hemoglobin (hemolysate)	20 mg/dL	0.4	-44
Lipemia Intralipid®	50 mg/dL 200 mg/dL	0.4	<10 -22

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm.

Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension X-pand® Cal Accept Guidelines
4. Dimension X-pand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure
6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Material Safety Data Sheets (MSDS)
11. Siemens Dimension Xpand® Limits Chart
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirement (Lab policy)
17. Critical Values (Lab policy)
18. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
19. Current package insert TBI Flex® Reagent Cartridge DF167
20. Current package insert DBI Flex® Reagent Cartridge DF125

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144.
2. Package Insert, TBI Flex® Reagent Cartridge DF167, Siemens Healthcare Diagnostics Inc., 04/07/2008.
3. Package Insert, DBI Flex® Reagent Cartridge DF125, Siemens Healthcare Diagnostics Inc., 04/07/2008.
4. Package Insert, TBI/DBI Calibrator, Siemens Healthcare Diagnostics Inc., 04/2008.

5. Package Insert, Unassayed Liquichek Chemistry Controls, Bio-Rad Laboratories, 10/2010.
6. Package Insert, Liquichek Pediatric Control, Bio-Rad Laboratories, 10/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None

DIMENSION® XPAND LIMITS CHART

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT
ACTM	µg/mL	2	2.0-600.0	3	2.0-900.0	Drug Calibrator II Level 1, or Acetaminophen Free Serum
ALB	g/dL	2.5	0.6-20.0	3	0.6-24.0	Water
ALC	mg/dL	1.5	0-450	3	5-900	Water
ALP	U/L	2.3	11-2,300	10	11-10,000	Enzyme Diluent
ALTI	U/L	3.5	6 – 3,500	10	6 - 10,000	Enzyme Diluent
AMY	U/L	2	0-1,300	10	0-6,500	Enzyme Diluent
AST	U/L	8	6-8000	10	6-10,000	Enzyme Diluent
BUN	mg/dL	1.5	0-225	3	0-450	Water
CA	mg/dL	1.7	5.0-25.5	3	5.0-45.0	Water
CKI	U/L	7	7-7000	20	7-20,000	Water
CL	mmol/L	N/A	N/A	N/A	50-200	Do NOT Dilute
CREA	mg/dL	2	0.0-40.0	3	0.0-60.0	Water
CRP	mg/dL	1.5	0.2-18.0	5	0.2-60.0	Water
CTNI	ng/mL	2.5	0.04-100.00	5	0.04-200.00	Water
DBI	mg/dL	1.9	0.1 – 30.4	5	0.1 - 80.0	Water
ECO2	mmol/L	N/A	N/A	2	5-90	Water
GLUC	mg/dL	1.5	0-750	5	0-2,500	Water
HCG	mIU/mL	200	1-200,000	5	1-1,000,000	Sample Diluent
K	mmol/L	N/A	N/A	N/A	1.0-10.0	Do NOT Dilute
LA	mmol/L	2	0.3-30.0	N/A	0.3-30.0	Do NOT Dilute
LIPL	U/L	1.5	10-2250	10	10-15,000	Water
MG	mg/dL	N/A	N/A	3	0.0-60.0	Water
MMB	ng/mL	2	0.5-600.0	5	0.5-1,500.0	Sample Diluent
NA	mmol/L	N/A	N/A	N/A	50-200	Do NOT Dilute
SAL	mg/dL	3	1.7 - 300.0	N/A	1.7 - 300.0	Do NOT Dilute
TBI	mg/dL	2	0.1 - 50.0	5	0.1 - 125.0	Water
TP	g/dL	1.9	2.0-22.8	3	2.0-36.0	Water
TSH	µIU/mL	2	0.01-100.00	5	0.01-250.00	Sample Diluent
UCFP (CSF)	mg/dL	2	6-500	10	6-2500	Water