

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k110780

B. Purpose for Submission:

New device

C. Measurand:

Direct and Total Bilirubin

D. Type of Test:

Quantitative, colorimetric

E. Applicant:

ELITech Group

F. Proprietary and Established Names:

ELITech Clinical Systems Bilirubin Total 4+1

ELITech Clinical Systems Bilirubin Direct 4+1

ELITech Clinical Systems ELICAL 2

ELITech Clinical Systems ELITROL I and II

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1110: Bilirubin (total or direct) test system

21 CFR 862.1150: Calibrator

21 CFR 862.1660: Quality control material (assayed and unassayed)

2. Classification:

Class II, Class II, and Class I reserved, respectively

3. Product code:
CIG, JIX, and JJY respectively
4. Panel:
75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 is intended for the quantitative in vitro diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

It is not intended for use in Point of Care settings.

Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 is intended for the quantitative in vitro diagnostic determination of direct bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

It is not intended for use in Point of Care settings.

Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for in vitro diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for in vitro diagnostic use in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

ELITech Clinical Systems Selectra Pro M analyzer

I. Device Description:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 is available as kit only. It consists of 2 reagents, “R1” and “R2”. Reagent R1 contains sulfanilic acid, Hydrochloric acid and cetrimide. Reagent R2 contains sodium nitrite.

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 is available as kit only. It consists of 2 reagents, “R1” and “R2”. Reagent R1 contains sulfanilic acid and Hydrochloric acid. Reagent R2 contains sodium nitrite.

ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.

ELICAL 2, Elitrol I and Elitrol II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV by FDA-approved methods or similar methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ABX PENTRA BILIRUBIN, TOTAL CP
ABX PENTRA BILIRUBIN, DIRECT CP
Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)
Roche Diagnostics Precinorm U and Precipath U

2. Predicate 510(k) number(s):

k060325 – Total and Direct Bilirubin
k033501 – Calibrator
k041227 – Controls

3. Comparison with predicate:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1

	Similarities and Differences	
Item	ELITech Clinical Systems BILIRUBIN TOTAL 4+1 (Candidate device)	ABX PENTRA BILIRUBIN, TOTAL CP (Predicate device)
Intended use	For quantitative in vitro diagnostic determination of	Same

	total bilirubin in human serum and plasma	
Indication for Use	Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block	Same
Assay protocol	Malloy-Evelyn modified method	Photometric test using 2,4-dichloroaniline (DCA) and a specific mixture of detergents
Composition	Reagent 1 : Sulfanilic acid 29 mmol/L Hydrochloric acid 67 mmol/L Cetrimide 37 mmol/L Reagent 2 : Sodium nitrite 5.8 mmol/L	Reagent 1 : Phosphate buffer 50 mmol/L NaCl 150 mmol/L Detergents , Stabilizers Reagent 2 : 2,4-Dichlorophenyl – diazonium salt 5 mmol/L HCl 130 mmol/L Detergent
Appearance of reagent	Liquid form, ready to use	Same
Sample type	Serum, Lithium heparin plasma	Same
Reagent storage	Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8°C and contamination is avoided.
Expected values	Adults : 0.3 – 1.2 mg/dL	Adults : 0.1 – 1.2 mg/dL
Instrument	Selectra ProM	ABX PENTRA 400
Measuring range	0.28 to 20.22 mg/dL	0.2 to 26.3 mg/dL
Limit of detection (LoD)	0.06 mg/dL	0.09 mg/dL
Limit of quantification (LoQ)	0.17 mg/dL	0.14 mg/dL
Precision	Within run Level 1.04 mg/dL CV=2.7% Level 3.67 mg/dL CV=0.8% Level 14.90 mg/dL CV=0.5% Total Level 1.04 mg/dL CV=4.0%	Within run Level 0.97 mg/dL CV=2.14% Level 5.13 mg/dL CV=0.99% Level 0.61 mg/dL CV=3.09% Level 0.85 mg/dL CV=2.23% Level 2.20 mg/dL CV=1.33%

	Level 3.67 mg/dL CV=2.0% Level 14.90 mg/dL CV=1.8%	Level 8.35 mg/dL CV=0.83% Total Level 1.0 mg/dL CV=4.04% Level 5.5 mg/dL CV=1.70% Level 0.8 mg/dL CV=5.97% Level 2.9 mg/dL CV=2.78% Level 9.1 mg/dL CV=2.20%
Method comparison	$y=0.924x + 0.02$ mg/dL $r^2= 0.998$ range: 0.30 to 20.22 mg/dL	$y=1.03x - 0.14$ mg/dL $r^2= 0.9965$ range: 0.3 to 25.8 mg/dL
Limitations	Triglycerides: No significant interference up to 2779 mg/dL Hemoglobin: No significant interference up to 500 mg/dL. Acetaminophen: No significant interference up to 30 mg/dL. Ascorbic acid: Concentration >2.0 mg/dL will interfere and cause erroneous results. Acetylsalicylic acid: No significant interference up to 200 mg/dL	Hemoglobin: No significant influence is observed up to 500 mg/dL. Triglycerides: No significant influence is observed up to 612.5 mg/dL
Calibration Frequency	28 days	10 days
On board stability	refrigerated area : 28 days	refrigerated area: 25 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

ELITech Clinical Systems BILIRUBIN DIRECT 4+1

	Similarities and Differences	
Item	ELITech Clinical Systems BILIRUBIN DIRECT 4+1 (Candidate device)	ABX PENTRA BILIRUBIN, DIRECT CP (Predicate device)
Intended use	For the quantitative in vitro diagnostic determination of	Same

	direct bilirubin in human serum and plasma	
Indication for Use	Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block	Same
Assay protocol	Malloy-Evelyn modified method	Photometric test using 2,4-dichloroaniline (DCA)
Composition	Reagent 1 : Sulfanilic acid 29 mmol/L Hydrochloric acid 67 mmol/L Reagent 2 : Sodium nitrite 5.8 mmol/L	Reagent 1 : Sulfamic acid 100 mmol/L EDTA-Na 2 0.1 mmol/L NaCl. 150 mmol/L Reagent 2 : 2,4-Dichlorophenyl – diazonium salt 0.5 mmol/L HCl 900 mmol/L EDTA-Na2 0.13 mmol/L
Appearance of reagent	Liquid form, ready to use	Same
Sample type	Serum, Lithium heparin plasma	Same
Reagent storage	Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8°C and contamination is avoided.
Expected values	< 0.2 mg/dL	Same
Instrument	Selectra ProM	ABX PENTRA 400
Measuring range	0.18 to 6.82 mg/dL	0.09 to 6.71 mg/dL
Limit of detection (LoD)	0.06 mg/dL	0.04 mg/dL
Limit of quantification (LoQ)	0.17 mg/dL	0.04 mg/dL
Precision	Within run Level 0.49 mg/dL CV=2.0% Level 1.89 mg/dL CV=0.6% Level 4.96 mg/dL CV=0.5% Total Level 0.49 mg/dL CV=4.7% Level 1.89 mg/dL CV=3.3%	Within run Level 0.90 mg/dL CV=0.67% Level 1.85 mg/dL CV=0.44% Level 0.23 mg/dL CV=3.23% Level 1.52 mg/dL CV=0.59% Level 7.88 mg/dL CV=2.69% Total

	Level 4.96 mg/dL CV=3.2%	Level 0.94 mg/dL CV=4.26% Level 2.02 mg/dL CV=4.22% Level 0.69 mg/dL CV=3.27% Level 3.83 mg/dL CV=2.98%
Method comparison	$y=0.988x + 0.07$ mg/dL $r^2= 0.974$ range: 0.25 to 6.55 mg/dL	$y=1.06x + 0.04$ mg/dL $r^2= 0.9928$ range: 0.09 to 6.71 mg/dL
Limitations	Triglycerides: No significant interference up to 2106 mg/dL Hemoglobin: No significant interference up to 125 mg/dL. Acetaminophen: No significant interference up to 30 mg/dL. Ascorbic acid: Concentration >0.3 mg/dL will interfere and cause erroneous results. Acetylsalicylic acid: No significant interference up to 200 mg/dL	Hemoglobin: do not use hemolyzed samples Triglycerides: No significant influence is observed up to 612.5 mg/dL
Calibration Frequency	28 days	10 days
On board stability	refrigerated area : 28 days	refrigerated area: 30 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

ELITech Clinical Systems Elical 2

Similarities and Differences		
Item	ELITech Clinical Systems Elical 2 (Candidate device)	Roche Calibrator (C.f.a.s) k033501 (Predicate device)
Intended Use/Indications for Use	For in vitro diagnostic use in the calibration of quantitative methods	Same
Format	Lyophilized calibrator based on human serum with constituents added as required	Same

	to obtain desired component levels	
Level	Single level	Same
Stability	<p>Lyophilized: store at 2-8° C and protect from light until the expiry date.</p> <p>After reconstitution: For total bilirubin: 6 hrs. at 15-25° C, 1 day at 2-8° C, 2 weeks at -15° C and -25° C. For direct bilirubin: 3 hrs. at 15-25° C, 8 hrs. at 2-8° C, 2 weeks at -15° C and -25° C.</p>	Same

ELITech Clinical Systems Elitrol I and II

Similarities and Differences		
Item	ELITech Clinical Systems Elitrol I/Elitrol II (Candidate device)	Roche Diagnostics Precinorm U and Precipath U (k041227) (Predicate device)
Intended Use/Indications for Use	For in vitro diagnostic use in quality control of quantitative methods	Same
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired component levels	Same
Level	Two levels	Same
Stability	<p>Lyophilized: store at 2-8° C and protect from light until the expiry date.</p> <p>After reconstitution: For total bilirubin: 8 hrs. at 15-25° C, 1 day at 2-8° C, 2 weeks at -15° C and -25° C. For direct bilirubin: 4hrs. at 15-25° C, 8 hrs. at 2-8° C, 2 weeks at -15° C and -25° C.</p>	Same

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline, Second Edition

CLSI EP09-A2 Method comparison and Bias estimation using patient samples;

Approved guideline, Second Edition

CLSI EP06-A Evaluation of the linearity of the measurement of quantitative procedures: a statistical approach

CLSI EP05-A2 Evaluation of precision performance of quantitative measurement methods; Approved guideline – Second Edition

CLSI EP17-A Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline

FR EN 13640:2002 Stability Testing of *in vitro* Diagnostic Reagents

“Code of Federal Regulations , Title 21, Volume 8, Part 807 –Establishment registration and device listing for manufacturers and initial importers of devices , revised as of April 1, 2008, 21CFR807”

“Abbreviated 510(k) submissions for In Vitro Diagnostic Calibrators, Feb 1999”

“Assayed and Unassayed Quality Control Material: Guidance for Industry and FDA Staff, June 2007.”

L. Test Principle:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1

In the presence of cetrimide, conjugated and unconjugated bilirubin react with diazotized sulfanilic acid to form azobilirubin. Determination of total bilirubin according to the following reactions:

Sulfanilic acid reacts with NaNO₂ to form Diazotized sulfanilic acid;

Bilirubin then reacts with Diazotized sulfanilic acid to form Azobilirubin

ELITech Clinical Systems BILIRUBIN DIRECT 4+1

In the absence of cetrimide, only conjugated bilirubin reacts with diazotized sulfanilic acid to form azobilirubin. Determination of direct bilirubin according to the following reactions:

Sulfanilic acid reacts with NaNO₂ to form Diazotized sulfanilic acid;

Conjugated bilirubin then reacts with Diazotized sulfanilic acid to form Azobilirubin

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was evaluated with one serum control material, one natural human serum sample, and one spiked human serum pool sample. Within-run and total precision results were obtained by performing two runs per day, two measures per run, for twenty days according to CLSI protocol EP5-A2 using

two Selectra Pro M instruments. The results are presented in the tables below:

For total bilirubin precision results:

Test levels	n	Mean (mg/dL)	Within-run CV (%)	Total CV (%)
Level 1	80	1.04	2.7 %	4.0 %
Level 2	80	3.67	0.8 %	2.0 %
Level 3	80	14.90	0.5 %	1.8 %

For direct bilirubin precision results:

Test levels	n	Mean (mg/dL)	Within-run CV (%)	Total CV (%)
Level 1	80	0.49	2.0 %	4.7 %
Level 2	80	1.89	0.6 %	3.3 %
Level 3	80	4.96	0.5 %	3.2 %

b. Linearity/assay reportable range:

For total bilirubin assay:

A linearity study of the total bilirubin assay was performed according to the CLSI EP6-A guideline. Two pools of patient serum samples were prepared to obtain one high and one low concentration of serum pools. A high sample was obtained by spiking the serum pool to obtain a high concentration of a sample pool (20.22 mg/dL). A low sample pool was prepared by diluting a low sample pool with buffered saline to obtain a low concentration of a sample pool (0.28 mg/dL). Using the high and low pooled samples, eleven levels of inter-mixtures were prepared according to the CLSI EP6-A guideline. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd, and 3rd order least square regressions. A first order linear regression was generated as follows:

$$Y=1.0074X - 0.04, r = 0.9997$$

The results of the study support the sponsor's claim that the total bilirubin assay has a measuring range of 0.28 to 20.22 mg/dL.

Dilution study:

The sponsor performed a 1:5 manual dilution study with 10 spiked samples using saline as the diluent. Ten samples with total bilirubin concentrations between 16.5 to 98.9 mg/dL were diluted 1:5. The % recovery between the expected values and observed values are within 10%. Therefore, the sponsor claimed that sample with total bilirubin concentration greater than the upper

claimed measuring range (20.22 mg/dL) can be diluted manually 1:5 with saline.

For direct bilirubin assay:

A linearity study of the direct bilirubin assay was performed according to the CLSI EP6-A guideline. Two pools of patient serum samples were prepared to obtain one high and one low concentration of serum pools. A high sample was obtained by spiking the serum pool to obtain a high concentration of a sample pool (6.82 mg/dL). A low sample pool was prepared by diluting a low sample pool with buffered saline to obtain a low concentration of a sample pool (0.18 mg/dL). Using the high and low pooled samples, eleven levels of inter-mixtures were prepared according to the CLSI EP6-A guideline. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd, and 3rd order least square regressions. A first order linear regression was generated as follows:

$$Y=1.0293X - 0.0259, r = 0.9992$$

The results of the study support the sponsor's claim that the total bilirubin assay has a measuring range of 0.18 to 6.82 mg/dL.

Dilution study:

The sponsor performed a 1:5 manual dilution study with 10 spiked samples using saline as the diluent. Ten samples with direct bilirubin concentrations between 5.4 to 32.3 mg/dL were diluted 1:5. The % recovery between the expected values and observed values are within 10%. Therefore, the sponsor claimed that sample with direct bilirubin concentration greater than the upper claimed measuring range (6.82 mg/dL) can be diluted manually 1:5 with saline.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

ELICAL 2 calibrator for total bilirubin and direct bilirubin is purchased from a commercially available source and relabeled (previously cleared in k033501) and is traceable to a NIST traceable material, SRM 916a.

ELICAL 2 calibrator is value assigned using multiple runs on two Selectra Pro M analyzers. The target value of ELICAL 2 calibrator is the mean of the observed values range. After validation of the target value, a confidence range (high and low values) is calculated. On-board calibration stability is 28 days for both total and direct bilirubin assays. Reconstituted calibrator stability for both analytes has been verified for the following temperatures and time limits. For total bilirubin: 6 hrs. at 15-25° C, 1 day at 2-8° C, 2 weeks at -15° C and -25° C. For direct bilirubin: 3 hrs. at 15-25° C, 8 hrs. at 2-8° C, 2 weeks at -15° C and -25° C.

Control material was purchased from commercially available sources and relabeled (previously cleared in k041227). ELITROL I and II control solutions are value assigned using two Selectra Pro M analyzers. Each sample is tested in triplicate over several days. The target value of Level I and II are the median of the observed values range. After validation of the target value, a confidence range (high and low values) is calculated. Reconstituted control stability for both analytes has been verified for the following temperatures and time limits. For total bilirubin: 8 hrs. at 15-25° C, 1 day at 2-8° C, 2 weeks at -15° C and -25° C. For direct bilirubin: 4hrs. at 15-25° C, 8 hrs. at 2-8° C, 2 weeks at -15° C and -25° C.

Reagent stability for the total bilirubin and direct bilirubin were evaluated on one Selectra analyzer with one lot of reagent using 4 controls and a linearity set for each measurand. Real-time stability study of the reagents supports shelf-life claims of 18 months when stored at 2 to 8°C. On board stability are 28 days for total and direct bilirubin. Protocol and acceptance criteria are found to be acceptable.

d. Detection limit:

The Limits of Blank (LoB), Detection (LoD) and Quantitation (LoQ) studies were conducted following CLSI EP17-A for total bilirubin and direct bilirubin. Two Selectra Pro M analyzers and two lots of the respective reagents were used. The LoBs were determined by analyzing a blank sample 60 times. The LoD and LoQ studies each used 4 serum pools (each measured 15 times) for the individual assays with a total of 60 measurements. The serum pools for the LoD had concentrations of the individual measurand approximately 4 times the LoB. LoQs were determined by analyzing 4 serum pools near the expected LoQ. Results are summarized below:

Assay	LoB	LoD	LoQ
Total bilirubin	0.04 mg/dL	0.06 mg/dL	0.17 mg/dL
Direct bilirubin	0.04 mg/dL	0.06 mg/dL	0.17 mg/dL

The total bilirubin assay has a measuring range of 0.28 to 20.22 mg/dL.

The direct bilirubin assay has a measuring range of 0.18 to 6.82 mg/dL.

e. Analytical specificity:

Testing for interfering substances was based on CLSI EP-7A for both total bilirubin and direct bilirubin assay. Testing was performed on various different concentrations for each interfering substances. Samples with increasing amounts of triglycerides, hemoglobin, acetaminophen, acetylsalicylic, and ascorbic acid were tested in triplicate and compared to the

same sample without the interfering substances. The sponsor defined non-significant interference as the highest level tested that does not cause >10% change between the tested samples and the control sample. Results are summarized in the tables below:

For total bilirubin assay: Two levels of analytes concentrations were tested (1.0 and 15.0 mg/dL)

	Highest concentration tested showing non-significant interference (mg/dL)
Triglyceride	2779
Hemoglobin	500
Acetaminophen	30
Acetylsalicylic acid	200
Ascorbic Acid	2.0

For direct bilirubin assay: Two levels of analytes concentrations were tested (0.5 and 4.5 mg/dL)

	Highest concentration tested showing non-significant interference (mg/dL)
Triglyceride	2106
Hemoglobin	125
Acetaminophen	30
Acetylsalicylic acid	200
Ascorbic Acid	0.3

Based on the interference study data, the sponsor has the following limitations in the labeling:

For total bilirubin assay:

Ascorbic acid concentrations greater than 2.0 mg/dL cause falsely elevated total bilirubin results.

For direct bilirubin assay:

Ascorbic acid concentrations greater than 0.3 mg/dL cause falsely elevated total bilirubin results.

Specimen requirement: Serum, free of hemolysis.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

For total bilirubin assay:

A method comparison study was performed using the Elitech total bilirubin reagent (on Selectra Pro M analyzer) and the Horiba ABX bilirubin total CP reagent (on Pentra 400 analyzer). A total of 100 serum samples were used, including 4 diluted samples. The sample range tested was 0.30 to 20.22 mg/dL. Result of the linear regression analysis is shown in the table below:

Slope (95%CI)	Intercept (95%CI)	R²
0.924 (0.918 to 0.929)	0.02 (-0.01 to 0.06)	0.998

For direct bilirubin assay:

A method comparison study was performed using the Elitech direct bilirubin reagent (on Selectra Pro M analyzer) and the Horiba ABX bilirubin direct CP reagent (on Pentra 400 analyzer). A total of 100 serum samples were used, including 10 diluted samples. The sample range tested was 0.25 to 6.55 mg/dL. Result of the linear regression analysis is shown in the table below:

Slope (95%CI)	Intercept (95%CI)	R²
0.988 (0.965 to 1.011)	0.07 (0.01 to 0.14)	0.974

b. *Matrix comparison:*

For total bilirubin assay:

A matrix comparison study with 45 paired serum and plasma (lithium heparin) samples were performed using one Selectra Pro M analyzer. 4 out of the 45 samples were spiked. Sample range tested was 0.35 to 18.66 mg/dL. Result of the linear regression analysis is shown in the table below:

Slope (95%CI)	Intercept (95%CI)	R²
1.023 (1.008 to 1.039)	-0.06 (-0.18 to 0.06)	0.995

For direct bilirubin assay:

A matrix comparison study with 40 paired serum and plasma (lithium heparin) samples were performed using one Selectra Pro M analyzer. 4 out of the 40 samples were spiked. Sample range tested was 0.20 to 5.84 mg/dL. Result of the linear regression analysis is shown in the table below:

Slope (95%CI)	Intercept (95%CI)	R²
0.953 (0.920 to 0.987)	0.05 (-0.06 to 0.16)	0.978

Based on the data, the sponsor claims that the lithium heparin is an acceptable anticoagulant for both assays.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Reference range is cited from the literature:

For total bilirubin: Serum, plasma: Adults: 0.3 to 1.2 mg/dL

Tietz, N.W. Clinical guide to laboratory test, 3rd Ed, (W.B. Saunders eds., Philadelphia USA), 1995.

For direct bilirubin: Serum, plasma: Adults: <0.2 mg/dL

Sherwin, J.E., Thompson, C., Liver function. Clinical Chemistry: Theory, Analysis, Correlation, 4th ed., and Kaplan, L.A., A.J., Kazmierczak, S.C., (Mosby Inc. eds, St. Louis USA), 2003, 493 and appendix.

It is recommended for each laboratory to establish and maintain its own reference values. The values given are used as guidelines only.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.