August 4, 2023

Trinity Biotech (Primus Corporation, dba Trinity Biotech)
Kaitlyn Eastman
Regulatory Supervisor
4231 E. 75th Terrace
Kansas City, Missouri 64132

Re: K222635
Trade/Device Name: Premier Resolution System
Regulation Number: 21 CFR 864.7415
Regulation Name: Abnormal Hemoglobin Assay
Regulatory Class: Class II
Product Code: GKA
Dated: August 30, 2022
Received: August 31, 2022

Dear Kaitlyn Eastman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222635

Device Name
Premier Resolution System

Indications for Use *(Describe)*
The Premier Resolution System is an automated High Performance Liquid Chromatography (HPLC) system which performs the separation of hemoglobin species in venous whole blood samples for the quantitative analysis of normal hemoglobin (A, A2, and F), and the qualitative detection of major variant hemoglobin S, C, D-Los Angeles, and E in adult, adolescent, children and infant populations. The assays are performed on venous whole blood samples collected in tubes containing K2EDTA as anticoagulant.

The Premier Resolution System is intended for Professional Laboratory Use only.

The Premier Resolution System is intended for use with analytical components and reagents provided by Trinity Biotech.

The Premier Resolution System is intended to be used in conjunction with other laboratory and clinical findings.

For In Vitro Diagnostic Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# Section 5: 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

## 1. Submitter / Sponsor

Trinity Biotech
4231 E. 75th Terrace
Kansas City, MO 64132 USA

Phone: 716.483.7423
Fax: 816.361.1974

Contact Person: Kaitlyn Eastman
Date Prepared: July 25, 2023

## 2. Device

Name of Device: Premier Resolution System
Classification Name: Abnormal Hemoglobin Assay
Regulation: 21 CFR § 864.7415
Regulatory Class: Class II
Product Code: GKA

## 3. Predicate Device

Bio-Rad Variant II β -thalassemia (K991127)

## 4. Device Description

The Premier Resolution System consists of a high performance liquid chromatographic analyzer, reagents, analytical column and software which allows for the fractionation and quantitation of fetal hemoglobin (Hb F), and hemoglobin A2 (Hb A2), and with fractionation and presumptive identification of abnormal hemoglobin variants. This is accomplished using the principles of ion-exchange (IEX) high performance liquid chromatography (HPLC).

## 5. Indications for Use Statement and Intended Uses

The Premier Resolution System is an automated High Performance Liquid Chromatography (HPLC) system which performs the separation of hemoglobin species in venous whole blood samples for the quantitative analysis of normal hemoglobin (A, A2, and F), and the qualitative detection of major variant hemoglobin S, C, D-Los Angeles, and E in adult, adolescent, children and infant populations. The assays are performed on venous whole blood samples collected in tubes containing K2EDTA as anticoagulant.

The Premier Resolution System is intended for Professional Laboratory Use only.

The Premier Resolution System is intended for use with analytical components and reagents provided by Trinity Biotech.

The Premier Resolution System is intended to be used in conjunction with other laboratory and clinical findings.

For *In Vitro* Diagnostic Use.

## 6. Comparison of Technological Characteristics with the Predicate Device

| Aspect or Feature | Predicate<br>Bio-Rad Variant™ II Beta Thalassemia K991127 | Premier Resolution System |
|---|---|---|
| **Intended Use** | The Variant™ II B-thalassemia Program is intended for the separation and area percent determinations of hemoglobins A2 and F and as an aid in the identification of abnormal hemoglobins in whole blood using ion-exchange high performance liquid chromatography (HPLC).<br><br>The Variant™ II B-thalassemia Program is intended for use only with the Bio-Rad Variant™ II Hemoglobin Testing System.<br><br>For *in vitro* diagnostic use only. | The Premier Resolution System is an automated High Performance Liquid Chromatography (HPLC) system which performs the separation of hemoglobin species in venous whole blood samples for the quantitative analysis of normal hemoglobin (A, A2, and F), and the qualitative detection of major variant hemoglobin S, C, D-Los Angeles, and E in adult, adolescent, children and infant populations. The assays are performed on venous whole blood samples collected in tubes containing K2EDTA as anticoagulant.<br><br>The Premier Resolution System is intended for Professional Laboratory Use only.<br><br>The Premier Resolution System is intended for use with analytical components and reagents provided by Trinity Biotech.<br><br>The Premier Resolution System is intended to be used in conjunction with other laboratory and clinical findings.<br><br>For *In Vitro* Diagnostic Use. |
| **Chemistry** | Ion Exchange HPLC | Ion Exchange HPLC |
| **Collection Tubes** | $K_2$EDTA, $K_3$EDTA | $K_2$EDTA |
| **Sample Tube Processing** | Aspiration of hemolysate from closed tube | Aspiration of whole blood from closed tube |
| **Sample Hemolysis** | Performed automatically by the system | Performed automatically by the system |
| **Automated Sample Introduction** | Continuous loading with sample racks | Continuous loading with sample racks |
| **Separation System** | Ion-exchange high performance liquid chromatography (HPLC) | Ion-exchange high performance liquid chromatography (HPLC) protein separation |

| Aspect or Feature | Predicate<br>Bio-Rad Variant™ II Beta Thalassemia K991127 | Premier Resolution System |
|---|---|---|
| | protein separation on analytical column based on ionic interaction with the column material and elution by buffer gradient with increasing ionic strength. | on analytical column based on ionic interaction with the column material and elution by buffer gradient with increasing ionic strength. |
| **Separation Unit** | Analytical Column | Analytical Column |
| **Analysis Throughput** | About 6 Minutes | About 4 Minutes - Quick Scan<br>About 8 Minutes - High Resolution |
| **Calibration** | A2 + F Calibrator | A2+F Calibrator |
| **Control** | A2+F Control | A2+F Control |
| **Use of Other Controls** | FASC Position Marker | FASC Position Marker |
| **Sample Identification** | Barcode on sample tube | Barcode on sample tube |
| **Absorbance wavelength** | About 413 nm | 413 nm |
| **Hb Variants Library** | Display and Operator Manual | Display and Operator Manual |

**7. Performance Data**

The following performance data were provided in support of the substantial equivalence determination.

**Correlation (Method Comparison)**

To establish equivalence, the method comparison study was conducted at three (3) professional external laboratory sites with both the Premier Resolution System and the Bio-Rad Variant™ II Beta Thalassemia. A total of 780 unique patient samples were collected and analyzed in both the Quick Scan and High Resolution assay modes. The following results are presented for the Premier Resolution Quick Scan and High Resolution assay modes:

**Premier Resolution Quick Scan Assay**

The Premier Resolution is comparable to the Bio-Rad Variant II for HbF on the Quick Scan Assay by a mean bias of -0.3 between the intervals of 1.1 to 48.9% with 160 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbA on the Quick Scan Assay by a mean bias of 0.7 between the intervals of 2.5 to 89.7% with 682 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbA2 on the Quick Scan Assay by a mean bias of 0.1 between the intervals of 1.6 to 6.1% with 602 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbS on the Quick Scan Assay by a mean bias of 0.3 between the intervals of 6.8 to 67.1% with 106 patient samples.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbC on the Quick Scan Assay by a mean bias of -1.1 between the intervals of 9.5 to 82.8% with 49 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbD-LA on the Quick Scan Assay by a mean bias of 1.6 between the intervals of 11.6 to 82.7% with 17 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbE on the Quick Scan Assay by a mean bias of -3.0 between the intervals of 5.5 to 70.4% with 25 patient results.

**Premier Resolution High Resolution Assay**

The Premier Resolution is comparable to the Bio-Rad Variant II for HbF on the High Resolution Assay by a mean bias of -0.4 between the intervals of 1.1 to 46.6% with 158 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbA on the High Resolution Assay by a mean bias of 2.4 between the intervals of 3.5 to 90.5% with 586 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbA2 on the High Resolution Assay by a mean bias of 0.1 between the intervals of 1.6 to 6.0% with 598 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbS on the High Resolution Assay by a mean bias of 1.3 between the intervals of 1.9 to 67.9% with 110 patient samples.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbC on the High Resolution Assay by a mean bias of -1.0 between the intervals of 10.2 to 82.5% with 49 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbD-LA on the High Resolution Assay by a mean bias of 2.7 between the intervals of 11.7 to 84.1% with 17 patient results.

The Premier Resolution is comparable to the Bio-Rad Variant II for HbE on the High Resolution Assay by a mean bias of -4.9 between the intervals of 5.3 to 66.7% with 25 patient results.

## Single Site Precision

The Single-Site precision study was conducted following *EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition*. Samples of varying concentrations of HbA, A2, and F were analyzed on the Premier Resolution using the Quick Scan and High-Resolution assay mode for the quantitation hemoglobin fractions. The retention time and relative retention time precision was also determined for each hemoglobin fraction. The 20x2x2 study design was conducted over 20 days, with two runs per day and two replicates per run. The study yielded 80 data points for each analyte to establish a balanced dataset.

**Single Site Precision - Quick Scan**

| Sample Description | N | Mean Value | Repeatability | | Between-Run | | Between-Day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| A High | 80 | 83.56 | 0.25 | 0.30% | 0.37 | 0.44% | 2.98 | 3.57% | 3.01 | 3.61% |
| A Mid | 80 | 51.24 | 0.35 | 0.68% | 0.15 | 0.30% | 0.25 | 0.50% | 0.46 | 0.89% |
| A2 Mid | 80 | 2.57 | 0.04 | 1.63% | 0.03 | 1.07% | 0.03 | 1.08% | 0.06 | 2.23% |
| A2 Low | 80 | 1.75 | 0.04 | 2.02% | 0.02 | 0.90% | 0.10 | 5.57% | 0.10 | 5.99% |
| F High | 80 | 11.38 | 0.05 | 0.43% | 0.03 | 0.26% | 0.10 | 0.92% | 0.12 | 1.05% |
| F Mid | 80 | 1.67 | 0.04 | 2.42% | 0.00 | 0.00% | 0.04 | 2.18% | 0.05 | 3.26% |
| S High | 80 | 74.63 | 0.33 | 0.44% | 0.18 | 0.24% | 0.55 | 0.74% | 0.67 | 0.89% |
| S Mid | 80 | 30.61 | 0.14 | 0.47% | 0.14 | 0.45% | 0.22 | 0.73% | 0.30 | 0.98% |
| C High | 80 | 81.22 | 0.41 | 0.50% | 0.43 | 0.53% | 0.23 | 0.28% | 0.63 | 0.78% |
| C Mid | 80 | 31.91 | 0.46 | 1.43% | 0.26 | 0.81% | 0.20 | 0.61% | 0.56 | 1.75% |
| D High | 80 | 69.98 | 0.70 | 1.00% | 0.71 | 1.01% | 0.86 | 1.23% | 1.32 | 1.88% |
| D Mid | 80 | 38.14 | 0.30 | 0.79% | 0.37 | 0.97% | 0.61 | 1.61% | 0.78 | 2.04% |
| E High | 80 | 81.22 | 1.38 | 1.70% | 0.00 | 0.00% | 1.85 | 2.28% | 2.31 | 2.84% |
| E Mid | 80 | 22.30 | 0.14 | 0.62% | 0.17 | 0.75% | 0.65 | 2.90% | 0.68 | 3.06% |

**Single Site Precision – High Resolution**

| Sample Description | N | Mean Value | Repeatability | | Between-Run | | Between-Day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| A High | 80 | 83.64 | 0.43 | 0.52% | 0.38 | 0.45% | 2.98 | 3.56% | 3.03 | 3.63% |
| A Mid | 80 | 50.60 | 0.41 | 0.81% | 0.48 | 0.94% | 0.30 | 0.59% | 0.69 | 1.37% |
| A2 Mid | 80 | 2.48 | 0.10 | 4.13% | 0.15 | 5.92% | 0.00 | 0.00% | 0.18 | 7.22% |
| A2 Low | 80 | 1.59 | 0.06 | 3.92% | 0.09 | 5.98% | 0.00 | 0.00% | 0.11 | 7.15% |
| F High | 80 | 11.11 | 0.12 | 1.07% | 0.03 | 0.27% | 0.37 | 3.31% | 0.39 | 3.49% |
| F Mid | 80 | 1.34 | 0.08 | 5.78% | 0.04 | 3.23% | 0.08 | 6.24% | 0.12 | 9.10% |

| Sample Description | N | Mean Value | Repeatability | | Between-Run | | Between-Day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| S High | 80 | 76.89 | 0.57 | 0.74% | 0.42 | 0.54% | 0.74 | 0.96% | 1.02 | 1.33% |
| S Mid | 80 | 32.01 | 0.30 | 0.92% | 0.23 | 0.73% | 0.39 | 1.22% | 0.54 | 1.69% |
| C High | 80 | 81.07 | 0.51 | 0.63% | 0.49 | 0.61% | 0.61 | 0.75% | 0.94 | 1.15% |
| C Mid | 80 | 32.84 | 0.44 | 1.34% | 0.00 | 0.00% | 0.50 | 1.52% | 0.67 | 2.03% |
| D High | 80 | 73.83 | 1.07 | 1.45% | 0.89 | 1.21% | 0.84 | 1.14% | 1.62 | 2.20% |
| D Mid | 80 | 39.80 | 0.34 | 0.84% | 0.23 | 0.58% | 0.33 | 0.84% | 0.53 | 1.32% |
| E High | 80 | 77.26 | 0.93 | 1.20% | 0.94 | 1.21% | 3.33 | 4.31% | 3.58 | 4.63% |
| E Mid | 80 | 22.46 | 0.13 | 0.57% | 0.22 | 0.98% | 0.66 | 2.93% | 0.70 | 3.14% |

## Multisite Precision

The Multisite Precision Study was conducted in accordance with *CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition*. A 3x5x5 study design was performed across three (3) external sites over five (5) days with five (5) replicates per day. Three (3) Premier Resolution Systems, one per site and Mobile Phase 1, 2, and Diluent reagents (one lot of each), analytical column, and precision samples for the study were provided to the external sites. The study assessed instrument-to-instrument, operator-to-operator and site-to-site precision.

**Multisite Precision - Quick Scan**

| Quick Scan | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample Description | N | Mean Value | Repeatability | | Between-Day | | Between-Site | | Reproducibility | |
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| FASC F | 75 | 17.16 | 0.09 | 0.52% | 0.27 | 1.55% | 0.82 | 4.80% | 0.87 | 5.07% |
| FASC A | 75 | 42.89 | 0.22 | 0.52% | 0.33 | 0.78% | 0.34 | 0.78% | 0.52 | 1.22% |
| FASC S | 75 | 12.87 | 0.07 | 0.51% | 0.06 | 0.50% | 0.09 | 0.69% | 0.13 | 0.99% |
| FASC C | 75 | 14.14 | 0.11 | 0.78% | 0.08 | 0.57% | 0.26 | 1.87% | 0.30 | 2.11% |
| A2+F I F | 75 | 2.94 | 0.04 | 1.33% | 0.04 | 1.39% | 0.12 | 4.17% | 0.14 | 4.59% |
| A2+F I A | 75 | 82.75 | 0.31 | 0.38% | 1.00 | 1.21% | 1.16 | 1.40% | 1.57 | 1.89% |
| A2+F I A2 | 75 | 3.11 | 0.04 | 1.17% | 0.06 | 2.04% | 0.06 | 2.08% | 0.10 | 3.15% |
| A2+F II F | 75 | 7.23 | 0.10 | 1.36% | 0.12 | 1.70% | 0.27 | 3.69% | 0.31 | 4.28% |
| A2+F II A | 75 | 45.53 | 0.24 | 0.52% | 0.24 | 0.53% | 0.27 | 0.60% | 0.44 | 0.96% |
| A2+F II S | 75 | 27.63 | 0.18 | 0.65% | 0.21 | 0.77% | 0.19 | 0.69% | 0.34 | 1.22% |
| A2 A2 | 75 | 1.63 | 0.03 | 2.12% | 0.03 | 1.80% | 0.05 | 2.92% | 0.07 | 4.04% |
| C-Trait C | 75 | 30.51 | 0.26 | 0.85% | 0.36 | 1.17% | 0.86 | 2.82% | 0.97 | 3.17% |
| D-Trait D | 75 | 35.03 | 0.20 | 0.57% | 0.34 | 0.96% | 0.58 | 1.64% | 0.70 | 1.99% |
| E-Trait E | 75 | 23.08 | 0.34 | 1.47% | 0.31 | 1.36% | 0.73 | 3.17% | 0.87 | 3.75% |

**Multisite Precision – High Resolution**

| High Resolution | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample Description | N | Mean Value | Repeatability | | Between-Day | | Between-Site | | Reproducibility | |
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| FASC F | 75 | 17.31 | 0.11 | 0.64% | 0.06 | 0.35% | 1.43 | 8.28% | 1.44 | 8.31% |
| FASC A | 75 | 43.97 | 0.26 | 0.60% | 0.04 | 0.08% | 0.30 | 0.68% | 0.40 | 0.91% |
| FASC S | 75 | 13.46 | 0.10 | 0.72% | 0.06 | 0.45% | 0.07 | 0.50% | 0.13 | 0.98% |
| FASC C | 75 | 14.30 | 0.17 | 1.17% | 0.07 | 0.47% | 0.15 | 1.05% | 0.24 | 1.65% |
| A2+F I F | 75 | 2.89 | 0.07 | 2.47% | 0.04 | 1.30% | 0.07 | 2.30% | 0.10 | 3.62% |
| A2+F I A | 75 | 85.21 | 0.32 | 0.37% | 0.97 | 1.14% | 0.62 | 0.73% | 1.20 | 1.40% |
| A2+F I A2 | 75 | 3.03 | 0.06 | 1.90% | 0.05 | 1.52% | 0.02 | 0.50% | 0.08 | 2.49% |
| A2+F II F | 75 | 7.29 | 0.08 | 1.11% | 0.09 | 1.27% | 0.29 | 3.93% | 0.31 | 4.27% |
| A2+F II A | 75 | 46.13 | 0.31 | 0.67% | 0.50 | 1.09% | 0.30 | 0.65% | 0.66 | 1.44% |
| A2+F II S | 75 | 28.99 | 0.19 | 0.66% | 0.32 | 1.09% | 0.37 | 1.28% | 0.52 | 1.81% |
| A2 A2 | 75 | 1.59 | 0.05 | 3.33% | 0.03 | 1.73% | 0.03 | 1.85% | 0.07 | 4.18% |
| C-Trait C | 75 | 30.53 | 0.22 | 0.71% | 0.26 | 0.86% | 0.31 | 1.03% | 0.46 | 1.51% |
| D-Trait D | 75 | 36.65 | 0.38 | 1.03% | 0.22 | 0.59% | 0.39 | 1.07% | 0.59 | 1.60% |
| E-Trait E | 75 | 22.25 | 0.27 | 1.23% | 0.30 | 1.35% | 0.46 | 2.06% | 0.61 | 2.76% |

**Limits of Detection**

The Limit of Detection Study was conducted in accordance with *CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition.* This study determined the limit of quantitation, blank, and lower limits of detection, for hemoglobins A, A2, F, S, C, D-Los Angeles, and E on the Trinity Biotech Premier Resolution. For the Limit of Detection evaluation, human whole blood samples containing 4 different levels of hemoglobins A, A2, F, S, C, D-Los Angeles and E were tested on the Premier Resolution System in the Quick Scan and High Resolution modes.

**Premier Resolution Quick Scan Assay**:

The limit of detection (LoD) for HbF is 0.2% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbF is 1.1% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbA is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbA is 2.3% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbA2 is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbA2 is 1.5% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbS is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbS is 1.0% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbC is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbC is 1.0% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbD-Los Angeles is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbD-Los Angeles is 1.5% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbE is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbE is 1.5% of the total area based on 60 determinations of low-level samples.

**Premier Resolution High-Resolution Assay**:

The limit of detection (LoD) for HbF is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbF is 1.1% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbA is 0.7% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbA is 2.2% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbA2 is 0.2% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbA2 is 1.5% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbS is 0.3% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbS is 0.9% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbC is 0.3% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbC is 1.7% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbD-Los Angeles is 0.1% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbD-Los Angeles is 1.4% of the total area based on 60 determinations of low-level samples.

The limit of detection (LoD) for HbE is 0.6% of the total area based on 60 determinations of low-level samples where the limit of blank (LoB) is set at 0.0% of the total area.

The limit of quantitation (LoQ) for HbE is 2.7% of the total area based on 60 determinations of low-level samples.

**Premier Resolution Analytical Specificity**

In studies on the analytical specificity of the quantitation of common hemoglobins by the Premier Resolution Analyzer, the Quick Scan assay and High Resolution assay were evaluated.

The analyte hemoglobins F, A, A2, S, C, D – Los Angeles, and E showed no statistical significance of interference with 20mg/dL of Bilirubin, 90mg/dL of acetylsalicylic, 85 UI concentration of Sodium Heparin anticoagulant,

85 UI concentration of Lithium Heparin anticoagulant, 9 mg/mL concentration of K2EDTA anticoagulant, and 9 mg/mL concentration of K3EDTA anticoagulant when analyzed in Quick Scan and High Resolution assay using Premier Resolution System.

Therefore, there is no interference with the quantitation of hemoglobins; HbF, Hb A, Hb A2, Hb S, Hb C, Hb D-Los Angeles and Hb E from the following interferent and concentrations stated in the table below:

| Interferent | Concentration |
|---|---|
| D-Glucose (HbF Only) | 5000mg/dl |
| Acetaldehyde | 20mg/dL |
| Lipemia (Triglycerides) | 4500mg/dL |
| Icterus (Unconjugated Bilirubin) | 20mg/dL |
| Icterus (Conjugated Bilirubin) | 10mg/dL |
| Acetylsalicylic Acid | 90mg/dL |
| Sodium Heparin | 85 UI |
| Lithium Heparin | 85 UI |
| K2EDTA | 9 mg/mL |
| K3EDTA | 9 mg/mL |

## 8. Conclusions

Performance testing has demonstrated that the similarities of the assays, the use of the same technology, ion exchange HPLC, and the excellent concordance between the two devices, it can be concluded that the Premier Resolution System is substantially equivalent to the predicate device, the Bio-Rad VARIANT II β Thalassemia. Based on the establishment of substantial equivalence, the safety and effectiveness of the Premier Resolution System has been confirmed.