Trinity Biotech

YOUR DIAGNOSTICS PARTNER

HAEMOGLOBINS | POINT OF CARE | INFECTIOUS DISEASE | CLINICAL CHEMISTRY

Premier Hb9210™ Resolution

The Premier Choice for Haemoglobinopathies

Introducing the Premier Hb9210™ Resolution

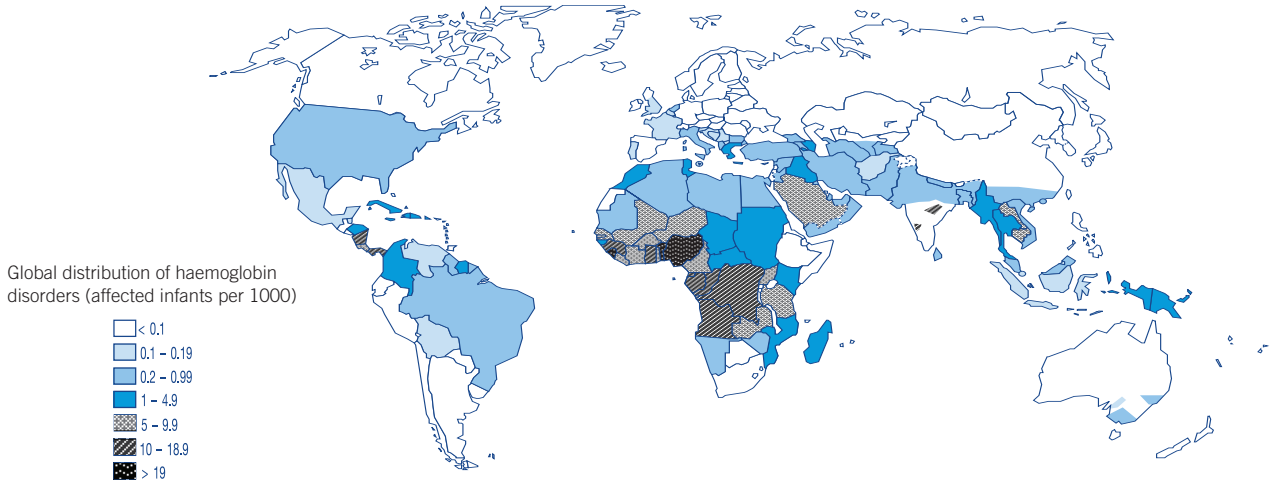
The most sophisticated solution in the world for haemoglobinopathies.

Features & Benefits

Technical Features	Ease of Use Features
Best-in-class Separation Technology Identify all common and most rare haemoglobin variants	**Fully Automated** 1-touch system operation, on-board QC, automated start-up/shutdown features
Calibrated A_2/F Standardised to calibrated A_2/F results in both Quick Scan and High Resolution run mode	**No Daily Maintenance** Maximise efficiency elsewhere in the laboratory
Complete A_2 Separation Both HbD & HbE fully separate from A_2, eliminating any potential interferences	**Chromatography Overlays** Initial interpretations performed using unique software feature
2-D Barcode Gradient Adjustment Automatically scan in dynamic gradient information with 2-D column barcode	**Consumables Not Lot-specific** No need to match specific lots of reagents and columns
Column Resolution Score No guesswork in changing the column – let the analyser do the work for you	**Large Colour Touchscreen Monitor** Highly sensitive for use with gloves, including a waterproof keyboard
FASC Position Marker Automated retention time adjustment to ensure proper peak labelling	**Intuitive Graphic User Interface** Easy to navigate, state-of-the art software platform
Comprehensive Variant Library Contains >90% of clinical cases – targeted growth of >300 variants by 2018	**Full Traceability** All reagents and consumables barcoded for full traceability

What are Haemoglobinopathies?

Haemoglobinopathies, which primarily consist of haemoglobin variants and thalassaemia, are inherited haemoglobin disorders originally characteristic of the tropics and subtropics in regions with a higher prevalence of malaria.



Haemoglobinopathies are becoming increasingly common worldwide due to vast global migration. Detection and prevention have become significant new challenges for laboratories throughout the world. But why is this clinically important?

S-trait & Sickle Cell Disease

The most common genetic red blood cell disorder in the world affecting millions around the globe. Those with Sickle Cell Disease will have distorted red blood cells which are sickle, or crescent shaped. Amongst other clinically significant symptoms, the disease can cause a low number of red blood cells (anaemia), repeated infections, and episodes of severe pain.

β thalassaemia

Reduction or absence in production of the β-globin chain which causes profound anaemia which if in Major form, kills untreated affected children before 3 years of age[1].

α thalassaemia

Reduction or absence in production of the α-globin chain which when in Major form, causes perinatal death, often with life-threatening obstetric complications for the mother[2].

Other Haemoglobin Variants

Currently >1,250 variations categorised, affecting approximately 7% of the global population. Pathological to varying degrees, potentially causing significant disease states requiring frequent treatment.

In an effort to prevent the spread of haemoglobinopathies, many countries are implementing neonatal and/or pre-marital screening programmes. The Premier Resolution provides the most modern, user-friendly solution on the market today for any routine.

1. Borgna-Pignatti C, et al. Survival and complications in patients with thalassemia major treated with transfusion and deferoxamine Haematologica 2004

2. Weatherall DJ, Clegg JB. Distribution and population genetics of the thalassaemias. 4th ed. Oxford: Blackwell Science; 2001.

The Premier Solution for Haemoglobinopathies

The Premier Hb9210™ Resolution is the only HPLC on the market with a dynamic gradient delivery system; accomplished using a proprietary, non-porous, weak cation exchange column. Best-in-class haemoglobin separation is performed in two different assay protocols (including an automated reflex option); both of which are standardised to a calibrated A_2/F reference material.

Quick Scan:

4.15 minutes – for calibrated A_2/F results and routine screening for haemoglobinopathies.

High Resolution:

8.2 minutes – for calibrated A_2/F results and best-in-class haemoglobin separation – presumptively identify rare variants and abnormal haematological conditions using the Variant Library and Chromatography Overlay features.

Reflex Option:

Run your routine in Quick Scan – any abnormalities will be automatically flagged by the Premier and reflexed to High Resolution mode – the only analyser on the market with automated reflex technology.

Identify all common haemoglobin variants and uncover other rare haemoglobin variants that less sensitive methodologies are unable to detect.

Simplify Your Daily Routine

With the Premier Hb9210™ Resolution, your daily routine has never been simpler. The following details an example of what a typical day might look like in your laboratory:

1. Instrument Start-up

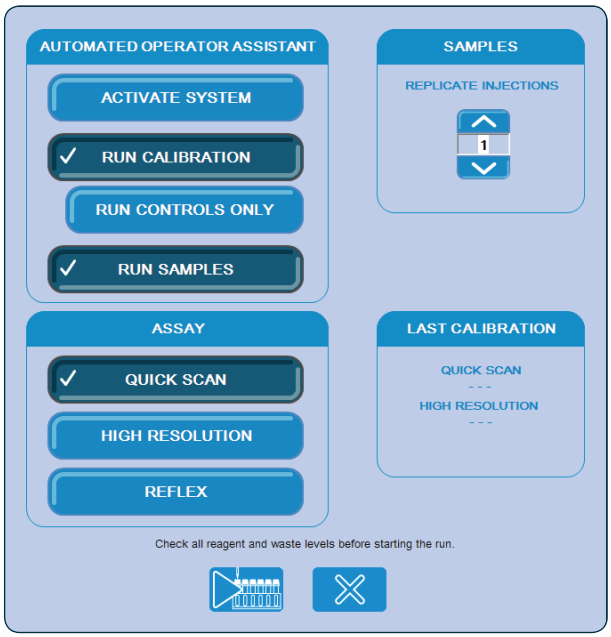
This function is completely automated – the Premier Hb9210™ Resolution will be ready to test patient samples as soon as you arrive in the laboratory.

Time Requirement: 0 Minutes

2. Loading Samples

Prepare and load your FASC and A_2/F QC and place them into the automated, on-board QC wheel. Load patient samples begin your run with the touch of 1 button.

Time Requirement: 2 Minutes



3. Running Samples

The Premier Hb9210™ Resolution will now run your routine. As a walk-away analyser – you are freed up to increase efficiency elsewhere in the laboratory.

Time Requirement: 0 Minutes – one touch operation, walk-away analyser[1]

4. Interpretation of Abnormal Peaks

Presumptive identification of haemoglobinopathies can be performed right in the laboratory using the Variant Library Chromatography Overlay feature within the software. Updates to the library will be released often and do not require a software update. The steps for performing this initial interpretation are as follows:

- The software will automatically flag abnormal peaks within a patient sample
- The software will automatically suggest potential matches within the Variant Library
- Adjust the Chromatography Overlays to arrive at a presumptive identification

Time Requirement: 5 Minutes per interpretation[2]

5. Instrument Shutdown

This function is completely automated – the Premier Hb9210™ Resolution will shut itself down either after a pre-programmed amount of time or at a certain time of day.

Time Requirement: 0 Minutes

Higher resolution, easier to use - why not simplify your routine?

1. Time estimations for running samples will vary depending on daily routine.
2. For further information on our Interpretation and Confirmation Support Services, contact your local Sales Representative

Modern Graphic User Interface

The Premier Resolution software was designed with the operator in mind. Coupled with a large, colour, touch-screen monitor which uses the same touchscreen technology as the most advanced smart phones and tablets – navigation has never been easier. Some of the key features are as follows:

- Real-time Sample Elution 1
- Within-run Review Pane 2
- Automated Start-up/Shutdown
- Touchscreen Calibration Not Required
- FASC Position Marker Window
- One-touch to Run Patient Samples 3
- Comprehensive Variant Library 4
- Chromatography Overlay Feature 5
- Customisable Sample Flagging System 6
- Levey-Jennings QC Reports
- System Status Dashboard 7
- 3rd Party QC Compatible
- 2-D Column Barcode Gradient Adjustment
- Barcoded Consumable Traceability 8

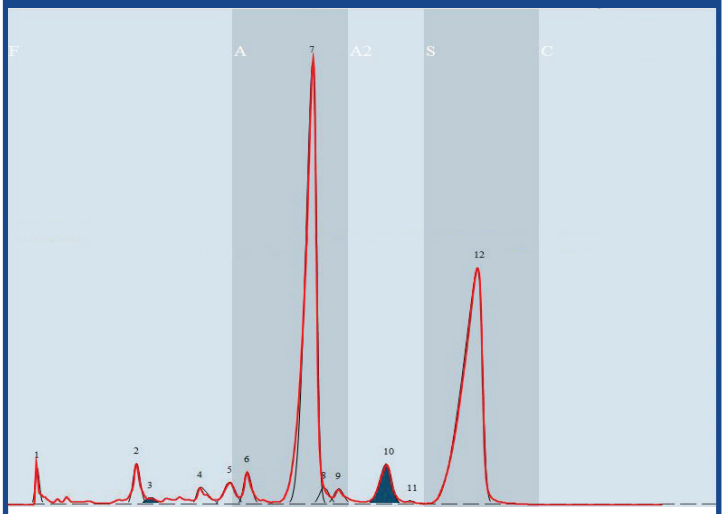
Interpretation and Confirmation Services

Do you require further support to identify unknown peaks? Or, have you potentially found a never-before-categorised haemoglobin variant? Trinity Biotech have a team of highly trained specialists and expert consultants who will review your results, provide professional advice and even perform confirmatory testing on molecular methods to ensure there are no doubts with any samples containing abnormal peaks.

Please contact your local sales representative for pricing and further information.

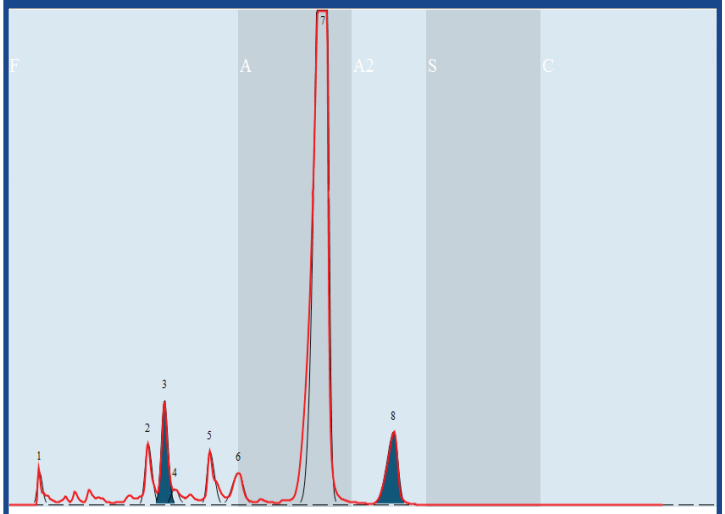
Example Reports

HbS



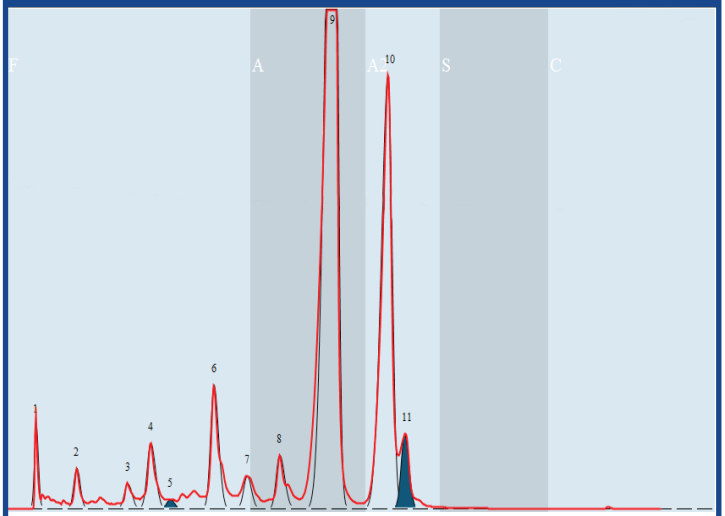
The most common genetic blood disorder, affecting millions around the world

β thalassemia



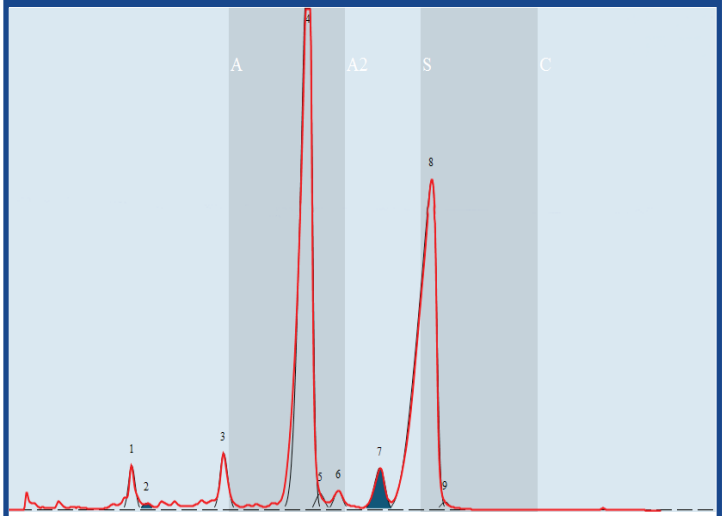
The more frequently occurring thalassemia – caused by a decrease in production of beta chains

HbE



Exceptional separation of HbE from A_2 in Quick Scan Mode – virtually interference free

HbD



Complete separation of HbD from A_2 in Quick Scan Mode – yielding precise and accurate A_2 results

The Premier Hb9210™ Resolution is the most sophisticated method on the market today for haemoglobinopathies. Best-in-class separation technology combined with state-of-the-art automation and ease-of-use features will provide your laboratory with the modern solution you are looking for. For more information on how you can simplify your haemoglobinopathy screening routine – please contact your local sales representative.

Specifications

Sample	Haemolysates made from whole blood or packed red blood cells. Blood can be fresh or thawed from frozen state
Elements of Analysis	Fractionation and/or quantification of foetal haemoglobin (HbF) and Haemoglobin A_2 (HbA_2)
Principle	Ion-exchange high performance liquid chromatography
Minimum Readable Division	Area percent = 0.01% Retention time = 0.001 minutes
Minimum Sample Requirement	10 µL (whole blood to make 1:150 haemolysate dilution, 0.5mL minimum haemolysate volume) 5 µL (packed red blood cells to make 1:300 dilution, 0.5mL minimum haemolysate volume) 0.5mL (mixed whole blood to make direct injection)
Sample Capacity	210 sample capacity for flexible, batch or continuous load
Assay Time	4.15 minutes in Quick Scan, 8.2 minutes in High Resolution
Analytical Column	Cation exchange
Sample Loop Temperature	Room temperature
Autosampler	Integrated 210 sample transport
Autoinjector	Delivers sample volume with <1% error with 5-µL injection volume
Detection	LED wavelength detector, 413 ± 2nm
Instrument Dimensions	Height: 74 cm (29”) Width: 54 cm (21”) Depth: 66 cm (26”)
Instrument Weight	62 kg (137 pounds)

Consumables

10-00-0001	Premier Hb9210 Resolution Analyzer
10-06-0001	Premier Resolution Analytical Column
10-06-0002	Premier Resolution Pre-Filter
01-03-0084	Premier Resolution Mobile Phase 1 Reagent (3.8L)
01-03-0085	Premier Resolution Mobile Phase 2 Reagent (3.8L)
01-03-0087	Premier Resolution Diluent Reagent (3.8L)
01-03-0088	Premier Resolution Wash Reagent (940mL)
01-03-0093	Premier Resolution Piston Wash Reagent (940mL)
01-04-0046	FASC Position Marker Kit
01-04-0044	A_2 +F Calibrator Kit
01-04-0045	A_2 +F Control Kit

To explore the Trinity Biotech solution that is right for your laboratory, please contact us now or visit our website at **www.trinitybiotech.com**

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