Added Value Tracked HbA1c

Webinar Summary

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Sysmex Added Value Tracked HbA1c Webinar

Dear Customer,

Thank you for attending the Added Value Tracked HbA1c Webinar. Please see below a short summary of the topics covered:

- Diabetes Mellitus: Statistics
  - 463 million people with Diabetes half of which do not know they have it.
  - 1 in 6 births affected by hyperglycaemia.
  - $727 Billion spent on diabetes globally (12% of the global GDP)
- Diabetes Mellitus: Overview
  - Type 1: characterized by deficient insulin production and requires daily administration of insulin.
  - Type 2: results from the body's ineffective use of insulin, accounting for around 90% of all cases of diabetes.
  - Gestational diabetes: hyperglycaemia with onset or first recognition during pregnancy.
- Diabetes Mellitus: Diagnostic Tests
  - Random Glucose Test - ≥ 11 mmol/L.
  - Fasting Blood Sugar Test – ≥ 7.0 mmol/L.
  - Oral Glucose Tolerance Test – ≥ 11.1 mmol/L following a 75 g oral glucose load.
  - Glycated Haemaglobin (HbA1c test) – ≥ 48 mmol/mol (equivalent to 6.5%).
- HbA1c: Overview of Haemoglobin
  - Haemoglobin is the major protein in the red blood cell (RBC) and is responsible for the transport of oxygen throughout the body.
  - In the normal ~120 day lifecycle of an RBC, circulating glucose molecules will react with the haemoglobin within the RBC to form glycated haemoglobin.
  - In the initial stage in the formation of glycated haemoglobin, there is an interaction between the haemoglobin and the blood glucose to form aldimine in a reversible reaction.
  - In the irreversible secondary step, aldimine is gradually converted into the stable ketoamine form.
- HbA1c: Haemoglobin fractions
  - During adulthood the major haemoglobin known as HbA comprises of about 97% of the total.
  - Minor components are Haemoglobin A2 (HbA2) and Foetal Haemoglobin (HbF) making up the rest in adult life (2 - 3.3% and 0.2 – 1.0% respectively).
  - 6% of total HbA is termed HbA1, which in turn is made up of HbA1a1, HbA1a2, HbA1b, and HbA1c fractions, defined by their electrophoretic and chromatographic properties.

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- Of those fractions, HbA1c is the most abundant and in health comprises approximately 5% of the total HbA fraction.

- HbA1c: Clinical use

  - **Diabetes control**: By checking the amount of HbA1c, the physician or consultant can determine how well diabetes is being controlled.
  - **Diagnosis of Diabetes**: ≥ 48 mmol/mol (equivalent to 6.5%) is diagnostic of Diabetes Mellitus.
  - Potential as a partial predictor for post-partum Diabetes.
  - Potential as a marker for dyslipidaemia, particularly hypertriglyceridaemia. This may mean it could be used to prevent cardiovascular events in high-risk patients.

- HbA1c: Other Benefits

  - Long term monitoring.
  - More convenience for the patient.
  - High pre-analytical stability.
  - Reduced day-to-day perturbations e.g. due to stress or illness.
  - Limitations include: diagnostic value for children is unclear, there is variation of the normal HbA1c value with different ethnicities, and associated interferences with anemias and thalassemias can also give false HbA1c values (can be method dependant).

- HbA1c: Methodologies

  - There are a number of methodologies available for the measurement of HbA1c, these methodologies can be split into two main groups.
  - Methods based on differences in charge include Ion-exchange chromatography (IEC) and capillary electrophoresis whilst methods based on structure include affinity chromatography, immunoassays that use antibodies to target specific structures of the Hb β chain, and enzymatic assays that use specific enzymes to cleave the N-terminal valine of HbA1c.

- Tosoh G11

  - The Tosoh G11 is based on the principle of HPLC with a cation exchange column named the TSKgel G11 Variant.
  - This column allows the separation of haemoglobin components into a total of six fractions.
  - A step gradient method is applied on the G11, to separate HbA1c fractions utilising three types of Variant Elution Buffers with different salt concentrations.
  - HbA1c (%) is determined as a relative percentage of the integrated area of HbA1c fraction against the sum of those of haemoglobin fractions, after being calibrated with the calibration curve established with Haemoglobin A1c calibrators.

- Added Value tracked HbA1c

  - Tosoh and Sysmex have collaborated to develop an automation offering through the integration of the Tosoh's G11 technology into Sysmex's XN-9000/9100 solution.
  - This integration now ensures that instead of separate EDTA tubes going to different lab areas or manually sorting the EDTA tubes for HbA1c or orders in the haematology work area, end-users can now process the EDTA tube orders, including HbA1c, in a fully automated way, in a single run.
  - The solution optimises workflow, decreasing the amount of time spent moving samples around the laboratory and provides the availability to perform other more important tasks as well.
  - Turnaround times are also improved as samples that require HbA1c analysis would be automatically transported to the G11 directly from the XN systems.
  - Integration should ensure there should be no outstanding HbA1c samples to be stored overnight and the risk of dropped and misplaced samples may also decrease due to there being less manual handling involved from laboratory staff.

- Added Value tracked HbA1c: Data Management

  - The Sysmex Extended IPU (EPU) data manager, assumes the complete order management for the EDTA tubes and routes the samples fully automatically in real time.
  - EPU is fully compatible with the G11 whether its standalone or integrated.
  - EPU will facilitate further workflow optimisation to make reviews safer, faster and more convenient.
  - All results, from blood counts to HbA1c values (including the chromatograms), can be displayed on a single screen offering maximum support to laboratory personnel.
  - EPU will also offer further productivity improvements with fully customisable autovalidaiton software and flags, repeat rules for flag triggers and full reagent traceability.

- Added Value tracked HbA1c: A few extra points…

  - It is not possible to take an existing standalone Tosoh G11 in the lab and attach it to a sysmex Haematology line as the systems are specifically manufactured for purpose.
  - Up to six (6) Tosoh G11 analysers can be integrated onto the Sysmex XN-9100 Haematology line.
  - The XN-Series can now support β-thalassaemia mode on the Tosoh G11 analysers.

A short feedback form has been sent via email. As part of our ongoing commitment to our customers, we continually look to improve our educational resources to ensure they meet our customer's needs/expectations and as our Added Value webinars are a new venture, we would greatly appreciate your feedback to help aid with this.
Summary and close

Kind Regards

Sysmex ICS Department