European Metrology Research Programme Delivering Impact





# Increasing access to anaemia testing

Anaemia is a common health condition that affects around 2 billion people worldwide. Timely treatment effectively restores health and can raise national productivity levels by as much as 20 %, according to the World Health Organisation. However, the current reference diagnostic test uses potassium cyanide to measure haemoglobin levels in blood, and the difficulties in procuring and disposing of this toxic compound are driving demand for alternative test methods.

#### Europe's National Measurement Institutes working together

The European Metrology Research Programme (EMRP) brings together National Measurement Institutes in 23 countries to address key measurement challenges at a European level. It supports collaborative research to ensure that measurement science meets the future needs of industry and wider society.

# Challenge

The haemiglobincyanide (HiCN) reference method has been the gold standard for measuring haemoglobin concentrations in blood, indicative of anaemia, for more than 50 years. Used around the world to diagnose anaemia and monitor response to treatment, the HiCN method is both effective and benefits from readily-available stable calibration standards.

The method uses potassium cyanide as a reagent to release haemoglobin from red blood cells - a spectrophotometer can then be used to determine haemoglobin concentration from the optical density of the solution. However, the disposal of large volumes of reagent containing cyanide creates a potential toxic hazard, and, in some countries, cyanide reagents are no longer available. In this case, alternative methods must be used and no reference method is available.

New methods are needed which can measure haemoglobin levels without the use of toxic chemicals, in addition to being both costeffective and easy-to-use. One promising alternative uses a nontoxic alkaline haematin detergent (AHD) and similar spectrometers to those used in the HiCN method. However, a standardised test procedure linking AHD measurements to the SI units is needed before the method can become an internationally-accepted reference method for the diagnosis and management of anaemia.

## Solution

The EMRP project *Metrology for metalloproteins* developed a reference material which links AHD measurements to the SI units for the first time. The project also developed an AHD measurement method protocol, which was tested in haematology laboratories to ensure its practicality. These results ensure that haemoglobin measurements produced by the test are reliable and comparable between users, and ultimately suitable for clinical use.

### Impact

The German standards organisation DIN is revising its existing standard on reference methods for analysing blood samples (DIN 58931) to incorporate the AHD method developed by the project, supporting its recognition and use as an alternative to the HiCN method. DIN has also proposed that CEN undertake a new work item on reference methods for determining haemoglobin concentrations in blood, an important first step towards the AHD method's inclusion in an international standard.

As part of the project, two reference laboratories, Instand e.V. and RfB (Reference Institute for Bioanalytics) were trained in the traceable AHD method and are implementing it in their laboratories. Both labs expect to provide benchmark values in the course of 2017 and conduct interlaboratory comparisons to ensure the quality of clinical results produced by labs using the AHD method.

The results of the project have removed major barriers preventing the AHD method from being internationally recognised as a reference method for the diagnosis of anaemia. When underpinned by international standards, the AHD method will be able to replace the HiCN reference method, removing the associated toxic waste stream and reducing the cost of anaemia diagnosis and management. This, in turn, will support timely treatment of this widespread condition, promoting personal health and increased productivity worldwide.

### Metrology for metalloproteins

The EMRP project *Metrology for metalloproteins* developed reference measurement methods to separate, identify and quantify a range of metalloproteins – proteins containing metallic ions. Metalloproteins play a crucial role in a range of biological processes, from respiration to photosynthesis. This makes their analysis a powerful tool in the diagnosis and treatment of diseases such as anaemia and cancer. The methods developed by the project will directly improve the quality of measurement results obtained from patient samples in clinical laboratories and ensure improved diagnosis and treatment outcomes.







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#### Claudia Swart

PTB, Germany +49 531 592 3150 | Claudia.swart@ptb.de