

Test Item Information Sheet (TIIS)

“Haemoglobin Quantification in Plasma” 2017_R1 Scheme

This sheet contains all information on **Plasma Test Items** that you should be aware of to conduct the above mentioned Scheme. **Please read carefully before any operation and/or test on the samples provided.**

Test Items Description

- Source material: Citrated human whole blood from healthy donor.
- Method of preparation: Plasma aliquoting.
- Medium: Not applicable.
- Date of preparation and any lot number (if applicable): July 2016.
- Biological hazard: The source material has been tested negative for negative for HIV (ELISA and PCR), HCV (ELISA and PCR); Syphilis (ELISA), HBsAg (ELISA), HBV (PCR), HAV (PCR), Parvovirus B19 (PCR).
- Biosafety level: All operations have been conducted in a BSL 2 environment.
- Method used for value assignment: Consensus by ISO17025/CLIA accredited laboratories, according to *The International harmonized protocol for the proficiency testing of analytical chemistry laboratories*, IUPAC technical report.
- Homogeneity and Stability information: Homogeneity and stability of the Test Items were controlled (in 2016 and 2017) and were found to be compliant with the requirements of *The International harmonized protocol for the proficiency testing of analytical chemistry laboratories*, IUPAC technical report.

Instructions to Prepare the Test Items for Testing

- Processing required of Test Item: No processing is required at receipt of Test Item.
- Any storage requirement between receipt and testing date: Store at **-80°C**. Testing should be performed within 1 week of receipt.
- Required temperature to perform the testing: Room temperature (18-24°C).
- Any step required/recommended for testing: Follow kit manufacturer's instructions.
- Any factor that may impact the testing negatively: Imprecision in pipetting, evaporation.

Particular Handling/Safety Requirements

- Potential risks of Test Item: Exempt of infectious risk.
- Individual protection equipment required: Standard laboratory (laboratory coat, gloves).
- In case of puncture or cuts: Abundantly wash with water and then disinfect during 10 minutes.
- In case of projection in the eye: Abundantly wash with water or physiologic serum during 5 minutes.
- In case of projection on the mucous membranes and skin: Wash with water.
- Measures to take in case of accidental dispersion: Pulverize disinfectant and clean the concerned surface.
- Waste elimination procedures: Waste generated by healthcare activities, to eliminate in incinerable plastic containers.

Schemes Specifications

- For each Test Item (Tube A and Tube B): Please measure **haemoglobin concentration (mg/ml)**.
- **How to test your samples:** Please test the Test Items following your usual routine testing method(s). IBBL strongly recommends using the “DetectX Hemoglobin Detection Kit” provided by Arbor Assays (catalog number K013-H1). If this kit is used, the online tool <http://www.myassays.com/viewshare.aspx?id=a2b93355-e472-4d1f-a53e-2e402b581156> is recommended for data analysis.
- You will be asked to report your results under the following methods: **ELISA, Spectrophotometry, Luminescent Spectroscopy, Hemoglobind, Other**.
- Please be ready to enter the following additional information while reporting your results:
 - **ELISA:** Kit used, Type of instrument.
 - **Spectrophotometry:** Type of instrument, measurement container/format (plastic cuvette, quartz cuvette, microspot, microplate or other).
 - **Luminescent Spectroscopy:** Luminescent complex used (Luminescent terbium complex, Other), Spectroscopy equipment used.
 - **Hemoglobind:** Type of instrument.
 - **Other:** Type of instrument, Method.
 - Please enter information on the dilution used (for each Test Item).
 - **Equipment performance verification:** Please enter information on the frequency of verification runs and the last verification date and results.

What Results and How to Submit Them

- For each Test Item, **you can perform the assay more than once per method** (according to your selected routine method), and submit more than one test result.
- Your results must be submitted online to the PT website <http://biospecimenpt.ibbl.lu/> using the login information (Laboratory Number and Password) provided to you via email after the registration to the “Haemoglobin Quantification in Plasma” Scheme.
- Please complete the questionnaire as accurately as possible, adding any relevant detail and comment in the appropriate comment section.
- Find out more information in the Results Submission Guidelines (<http://www.ibbl.lu/ibbl-bioservices/biospecimen-proficiency-testing/>).

Timelines for Returning Results

<i>Results submission</i>	<i>Data analysis & Report preparation</i>	<i>Reports available</i>
27 OCT 2017, latest	30 OCT 2017 – 30 DEC 2017	15 JAN 2018

In case of doubts in the completion phase, please contact IBBL at ISBERPT@ibbl.lu