

Test Item Information Sheet (TIIS)

“DNA Quantification and Purity” 2020_R1 Scheme

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

Test Items Description

- Source material: Whole blood.
- Method of preparation: DNA extracted by a magnetic bead-based method.
- Medium: 10mM TrisHCl, pH 7.8 – 8.2, volume of 50 µL.
- Date of preparation and any lot number (if applicable): June 2018, August 2019.
- 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 mean from Participants.
- Homogeneity and Stability information: Homogeneity and stability of the Test Items were controlled in July 2018 and September 2019 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: Dilution may be required for certain Test Items (this will have to be determined by the participant laboratory).
If you plan to report results under the **Unchained Labs Lunatic** (previously Trinean spectrophotometer with cDROP Software), please ensure you have correct software protocol on your computer. Please contact to request the protocol at Service@trinean.com.
- 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, Tube B and Tube C): Please measure **DNA concentration (ng/μl)** and **DNA 260/280 ratio** (if your method allows).
- How to test your samples: Please test the Test Items following your **usual routine testing method(s)**.
- You will be asked to report your results under the following methods: **Spectrophotometry, Spectrofluorometry, Microfluidic Electrophoresis, Lunatic** (previously Trinean spectrophotometer) and **Other**.
- Please be ready to enter the following additional information while reporting your results:
 - Spectrophotometry: Type of instrument, measurement container/format (plastic cuvette, quartz cuvette, microspot, microplate or other).
 - Spectrofluorometry: Type of instrument, measurement container/format (cuvette, microplate, tube, other), fluorochrome (ADyNA 515, YOYO-1, Hoechst 33258, Hoechst 33342, Hoechst 34580, SYBR Green, EvaGreen, PicoGreen, Other), wavelength excitation (485, 352, 350, 392, 484, 500,491, other), wavelength emission (515, 461, 440, 521, 530, 509, 528, other).
 - Microfluidic Electrophoresis: Type of instrument (Agilent Bioanalyzer, Biorad Experion, PerkinElmer Labchip GX, QIAGEN QIAxcel, other), type of chip.
 - Lunatic: Type of container (DropPlate S, DropPlate D+, other).
 - 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 and How to Submit

- 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 “DNA Quantification and Purity” Scheme.
- Please complete the questionnaire as accurately as possible, adding any relevant detail and comment in the appropriate comment section.

Timelines

<i>Results submission</i>	<i>Data analysis & Report preparation</i>	<i>Reports available</i>
20 NOV 2020, <u>latest</u>	23 NOV 2020– 22 JAN 2021	26 FEB 2021

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