

Test Item Information Sheet (TIIS)

“DNA Integrity” 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, September 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).
- Any factor that may impact the testing negatively: Prolonged light exposure of reagents; DNA contamination of Test Item; Organic component contamination of Test Item; Prolonged exposure to room temperature of Test Item.

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: Pulverise 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 integrity**.
- How to test your samples: Please test the Test Items following your **usual routine testing method**.
- You will be asked to report your results under the following methods: **Agilent TapeStation (DIN)**, **LabChip GX assay (GQS)**, **Fragment Analyzer™ (GQN)**, **QIAxcel System**, **Other (DQN)**.
- Please be ready to enter the type of instrument used while reporting your results under “Other”.
- 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 results.
- 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 Integrity” 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