Inhibition Panel – Lipaemic Specimens

Intended Use
The lipaemic specimens are designed to perform standard interference testing by diagnostic manufactures and researchers during assay development, evaluation and post-marked surveillance. The panel is suited for execution of routine investigations for the survey of inhibition effects by triglycerides in serologic/immunologic/biochemical assays as well as in nucleic acid amplification techniques (NAT). This panel is for Research Use Only.

Product Description
The most frequently performed interference studies are for the following serum indices: haemolysis, lipaemia and icterus.[1] Beside haemolysis, lipaemia (high triglyceride values) and increased bilirubin concentrations may also interfere with determinations, whereby bilirubin is the second most common interference after haemolysis.[2,3] The lipaemic specimens consist of human sera with increased values of triglycerides (> 200 mg/dL).

The lipaemic specimens are present in negative, low, medium and high concentrations. The matrix of the samples is serum gained from five different donors. Increasing concentrations of triglycerides from lipaemic CPD-plasmas were added to the sera. The samples do not contain any preservative. The final concentration of the samples was determined by employing a Roche/Hitachi cobas® 6000 analyzer.

Article Code	Components	Concentration Range	Quantity
IHL-005	Lipaemic serum negative	< 200 mg/dL	each 1.0 mL
	Lipaemic serum low	200 – 399,9 mg/dL	
	Lipaemic serum medium	400 – 699,9 mg/dL	
	Lipaemic serum high	> 700 mg/dL	

The panel with 5 individuals (Article Code: IHL-005) contains the corresponding quantity 20 x 1.0 mL. All components are ready to use.

The Inhibition Panel provides great flexibility in usage and can be used for several evaluation processes.

Storage and Stability
The Inhibition Panel must be stored at or below -20°C. It is recommended to store the product at -20°C to -40°C to ensure long-term stability. The specimens can be aliquoted in smaller volumes to avoid multiple freeze/thaw cycles. After usage, the samples should be frozen immediately to avoid the depletion and loss of activity. Ensure proper storage and limit exposure time to room temperature.

Instructions for Use
The Inhibition Panel was designed for usage with any assay system, which detects analytes derived or stored in whole blood or blood derivatives. All components are ready to use and if necessary, only the respective analyte has to be added into the specific matrix. It is recommended that the analyte should always be added with an equal volume/concentration, so that inhibition/non-inhibition effects (interference/non-interference claims) of the extraction and/or assay system are consistently verified.

The lipaemic specimens should be thawed at room temperature and mixed by gently inverting or shaking to ensure homogenous suspensions. Avoid foaming and contamination of components when opening and aliquoting. After usage, return the samples immediately to storage conditions to avoid long periods of storing at room temperature. The analyte must be in a physiologic buffer, plasma, serum or other blood derivative to be compatible with the panel components.

The analyte can be added directly to the specimen vials, or the specimens can be aliquoted in smaller volumes and then spiked within the desired range, depending on the concentration that is used for spiking. Spiked samples shall contain maximally 10% spike material to avoid interferences.

After the analyte is spiked, proceed with the samples as described by extraction or assay instructions from manufacturer. Follow the appropriate instructions and recommendations for safe handling and testing of human material.

Limitations

The Inhibition Panel – lipaemic specimens are not intended to replace internal diluents, controls, standards or calibrators of *in vitro* diagnostic (IVD) test kits. Furthermore, it is not recommended for blood bank screenings. This panel is for Research Use Only and not for human or animal diagnostics, or for therapeutic use.

Do not use this product in the event of microbial contamination. If this product is used in tests, please follow the exact instructions of the manufacturer. Any deviations from the recommended procedures may produce unreliable results.

It should be noted that this product is derived from native human material. A part of the lipaemic plasma is CPD-plasma and contains glucose as well as phosphate, which may react with glucose assays and detect incorrect values, so that interference from triglycerides is erroneously indicated.

Each laboratory has the responsibility to ascertain the suitability of the Inhibition Panel components for its application and to establish their own guidelines for interpretation of results. Data are provided for informational purpose. It is not claimed that others can duplicate test results exactly.

Precautions and Disposal Note

Although whole source material has been tested negative/non-reactive for anti-HIV, anti-HCV and HBsAg, they should be considered as potentially infectious, since no testing method can absolutely exclude the potential danger of infection. Treat this material with the same precaution as potentially infectious material.[4,5]

During the processing of the samples, longer refrigeration times of one to three days may lead to an increase or reduction of certain substances. All material should be handled and discarded in a safe manner that complies with local and national regulations.

References

1. Dimeski G., Interference Testing. Clin Biochem Rev. 2008 Aug; 29 Suppl 1:S43-48.

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4. Ausschuss für Biologische Arbeitsstoffe, Technische Regeln für Biologische Arbeitsstoffe TRBA 100: Schutzmaßnahmen für Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien; Ausgabe Oktober 2013, GMBl 2014, Nr. 51/52 vom 17.10.2013, Änderung vom 30.06.2014, GMBl Nr. 38, http://www.baua.de/cae/servlet/contentblob/673098/publicationFile/48545/TRBA-100.pdf

5. Richtlinie 2000/54/EG des Europäischen Parlaments und des Rates über den Schutz der Arbeitnehmer gegen Gefährdung durch biologische Arbeitsstoffe bei der Arbeit (Siebte Einzelrichtlinie im Sinne von Artikel 16 Absatz 1 der Richtlinie 89/391/EWG), vom 18. September 2000 (ABl. EU Nr. L 262 S. 21) http://www.gaa.baden-wuerttemberg.de/servlet/is/16050/2_1_07.pdf