Inhibition Panel – Icteric Specimens

Intended Use
The icteric specimens are designed to perform standard interference testing by diagnostic manufacturers and researchers during assay development, evaluation and post-market surveillance. The panel is suited for execution of routine investigations for the survey of inhibition effects by bilirubin in serologic/immunologic/biochemical assays as well as 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, lipemia and icterus.[1] Beside haemolysis, lipemia and increased bilirubin concentrations may also interfere with determinations, whereby bilirubin is the second most common interferent after haemolysis.[2,3] The icteric specimens consist of human sera with increased values of bilirubin.

The Inhibition Panel consists of 20 members. The icteric specimens are present in negative, low, medium and high concentrations. The negative concentration is based on the endogenic values of the sera gained from five different donors. The icteric sera were synthetically produced by adding conjugated and unconjugated bilirubin, thereby imitating natural occurring, icteric patient samples. No preservatives were added. For measurements, a Roche cobas® 6000 c501 analyzer was used.

Article Code	Components	Concentration Range	Quantity
IHI-005	Icteric Serum negative	< 5 mg/dL	each 1.0 mL
	Icteric Serum low	5 - 15 mg/dL	
	Icteric Serum medium	15 - 25 mg/dL	
	Icteric Serum high	25 - 40 mg/dL	

All components are ready to use, if requested only the analyte has to be added into the specific matrix in the required concentration.

The Inhibition Panel provides great flexibility in usage in that any sample preparation platform and subsequent analytical assay may be validated. The volumes of the final samples spiked with analyte and/or the final concentration of analyte may be adjusted by end user so that they are within requested levels for the assay of interest.

Storage and Stability
The Inhibition Panel is stable until the expiration date, provided it is unopened and stored at a minimum of -20°C. It is recommended to store the product at -20°C to -80°C to ensure highest quality. The specimens can be aliquoted in smaller volumes to avoid multiple freeze/thaw cycles. After usage, promptly refreeze to avoid leaving the product thawed for a longer period of time. A minimal loss of activity is possible. Bilirubin is sensitive to light and oxygen and may degrade more quickly than other components. Ensure proper storage and limit exposure time.

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 specimens are ready to use and only the analyte has to be added into the specific matrix in requested concentration. 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 icteric specimens should be thawed at room temperature and extensively mixed by inverting to ensure homogenous suspensions. Avoid foaming and contamination of

components when opening and aliquoting. After usage, return immediately to storage conditions to prevent long periods of thawing. The analyte has to be in a physiologic buffer, plasma, serum or other blood derivative to be compatible with the panel specimens.

The analyte can be added directly to the specimen vials, or the specimen can be aliquoted in smaller volumes and then spiked to a volume within the range of 1% to 50% of the total volume, depending on the concentration that is used for spiking. It should be noted that the initial concentration of components decreases accordingly. The added volume of the analyte should not exceed more than 50% of the total volume, as this will reduce the effectivity range of the potential interfering substance.

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 materials.

Limitations

The Inhibition Panel – icteric specimens are not intended to replace internal diluents, controls, standards or calibrators of *in vitro* diagnostic (IVD) test kits nor for blood bank screening. This panel is for Research Use Only and not for human or animal diagnostics, or for therapeutic use.

Do not use this product beyond the expiration date. In the event of microbial contamination or high turbidity, do not use. If this product is used in tests, please follow the exact instructions of the manufacturer. Any deviations from the manufacturer instruction for use may produce unreliable results.

Each laboratory has the responsibility to ascertain the suitability of the Inhibition Panel components for its particular application and to establish their own guidelines for interpretation of results. Data are provided for informational purpose. It is not claim 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 by CE-marked tests, 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 in, or reduction of certain substances by degradation processes. All material should be handled and discarded in a safe manner that complies with local and national regulations and will inactivate pathogenic agents.

References

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