Tumor Markers (Information Catalogue)

PURPOSE

CBQAP aims to reduce the high variability observed in routine diagnostic testing. The Tumor Markers module, part of the CBQAP proficiency testing, will help reduce the variability observed and ensure that the results produced showcase accurate description of the participant testing.

DISCLAIMER

CBQAP shall strictly maintain participant confidentiality. Any participant detail shall not be revealed to other participants. The data gathered from participants will only be used for analysis and research purposes.

Participants must test the samples(s) as per their routine diagnostic testing. The tests should be performed on the same method and analyser as mentioned in the CBQAP enrolment. Participants are advised not to share their webpage credentials, reports and other sensitive information.

SAMPLE CONTENT

Sample provided in this module comprises an amber colored glass vial containing lyophilised serum.

The sample has been screened and found to be negative for tests such as Hepatitis B, Hepatitis C, and HIV. The bottles are labelled with the respective program numbers for identification. For the Tumor Marker program, the bottle will be labelled as **"Tumor Markers Module"** and will comprise of program code starting with **"TM"**.

STORAGE

Samples are to be stored at a temperature of 2-8˚C. The sample can withstand a temperature of -20˚C. Sample remains stable when kept at 2-8˚C till the given expiration date. Once opened and reconstituted the sample remains stable in liquid form for 5 days at 2-8˚C, provided repeated freeze thawing is refrained.

PRECAUTIONS

⚠ Biological source material. Treat as potentially infectious.

Any unexpected results, abnormal sample characteristics, or suspected reagent issues should be promptly reported and investigated before proceeding further.

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PROTOCOL

DILUENT TO BE USED: Distilled Water

1. The sample provided by CBQAP should be treated as a patient sample and all protocols for testing the sample(s) should be carried out according to routine diagnostic procedures.
2. Take the vial labelled **"Tumor Marker Module"**. Open the metallic seal and then carefully open the rubber cap.
3. Reconstitute with exactly 2 mL of diluent and keep for 30 minutes at room temperature.
4. Test for the markers enrolled in the CBQAP program in the analyzers and method registered.
5. After testing, discard the sample and the vials as per the routine diagnostic procedures.

A total of four samples to be assayed over a twelve-month period, with one sample tested per quarter. Each sample is labelled accordingly, by which results should be submitted to CBQAP.

LIMITATIONS

1. This product should not be used past expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial and report the same.
3. This product is not intended for use as a standard.
4. Serum components may interfere with assay signal.

RESULT REPORTING & DATA SUBMISSION REQUIREMENTS

1. All test results shall be submitted through the CBQAP online portal within the specified timeline. The same will be made available shortly.
2. Results that are not reported will be excluded from statistical analysis and considered unacceptable.
3. Samples yielding results beyond the analytical measurement range of the method shall be managed in accordance with established laboratory procedures for handling out-of-range values.
4. Only results submitted on or before the assigned due date shall be included in the evaluation.
5. Late submissions may be considered; however, penalties may be applied at the end of the evaluation cycle.
6. Late submissions shall be flagged in the revised or updated analytical reports.
7. Results submitted after the closure of the evaluation cycle shall not be accepted under any circumstances.