HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of CA 19-9 Level		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To illustrate the necessary steps required for performing CA 19-9 assay on COBAS e411

2. DEFINITONS:

2.1 CA 19-9 (carbohydrate antigen 19-9 or sialylated Lewis (a) antigen) is a biomarker which is primarily used in the management of pancreatic cancer patients in addition to other diagnostic methods.

3. POLICY:

3.1 No data exist today which support the use of CA 19-9 in screening for malignancies, also concerning the fact that approximately 6 % of the population belong to the Lewis (a-/b-) blood group, lacking the antigenic determinant CA 19-9 and will therefore not release CA 19-9 even when a malignancy is present. This must be considered when interpreting the findings.

3.2 Among non-malignant conditions, obstructive jaundice is frequently associated with increases in CA 19-9 and unspecific elevation of CA 19-9 in serum reflects both inflammatory hypersecretion and leakage of biliary mucins into serum. CA 19-9 levels have also been reported in benign diseases like cystic fibrosis, hydronephrosis, and Hashimoto's thyroiditis.

3.3 In pancreatic cancer, levels > 100 U/mL are highly suggestive of un- resectable or metastatic disease and levels < 100 U/mL imply a likely resectable disease.

3.4 The European Group of Tumour Markers (EGTM) advice that CA 19-9 may be used as a diagnostic aid and for monitoring therapy in patients with pancreatic adenocarcinoma.13 CA 19-9 has been found to be prognostic for survival following resection of pancreatic ductal adenocarcinoma.

4. PROCEDURE:

4.1 **Principle:** Sandwich principle (for details refer to Company Leaflets of reagents).

4.2 **Sample:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-heparin, K2-EDTA and K3-EDTA plasma.

4.2.1 Do not use sodium citrate plasma. Criterion: Slope 0.9-1.1 + coefficient of correlation ≥ 0.95.

4.2.2 Stable for 14 days at 2°-8°C, 5 days at 20°-25°C, 3 months at -20°C (± 5°C). Freeze only once.

4.3 **Method:** See policy of loading sample on machine (Ref: Operative Manuals' of COBAS e411.

4.4 **Calculation:** The analyser automatically calculates the analytic concentration of each sample in U/mL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** <34 U/Ml

4.7 **Limitations:** interference

4.7.1 The assay is unaffected by icterus (bilirubin < 1129 µmol/L or < 66 mg/dL), hemolysis (Hb < 1.4 mmol/L or < 2.2 g/dL), lipemia (Intralipid < 1500 mg/dL) and biotin (< 100 ng/mL or < 409 nmol/L).

4.7.2 Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

4.8 **Measuring range:** 0.600-1000 U/mL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as < 0.600 U/mL. Values above the measuring range are reported as > 1000 U/mL (or up to 10000 U/mL for 10-fold diluted samples).

5. MATERIALS AND EQUIPMENT:

5.1 **Reagent:** For preparation see package insert:

5.1.1 **M:** Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL, preservative.

5.1.2 **R1:** Anti-CA 19-9-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-CA 19-9 antibody (mouse) 3 mg/L, phosphate buffer 100 mmol/L, pH 6.5; preservative

5.1.3 **R2:** Anti-CA 19-9-Ab~Ru (bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-CA 19-9 antibody (mouse) labelled with ruthenium complex 4 mg/L; phosphate buffer 100 mmol/L, pH 6.5; preservative.

5.2 **Calibration:**

5.2.1 Every Elecsys reagent set has a barcoded label containing specific information for calibration of the reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

5.2.2 Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

5.2.3 Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

5.2.4 Renewed calibration is recommended as follows:

5.2.4.1 After 8 weeks when using the same reagent lot.

5.2.4.2 After 7 days when using the same reagent kit on the analyser.

5.2.4.3 As required: e.g. quality control findings outside the defined limits.

5.3 **Quality control:**

5.3.1 For quality control, use PreciControl Tumor Marker In addition, other suitable control material can be used.

5.3.2 Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

6. RESPONSIBILITIES:

6.1 Hormone shift on charge is responsible for, running calibration and control and samples of CA 19-9.

6.2 Hormone staff are responsible for running CA 19-9 samples every morning.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyser

8.2 Company Leaflets of reagents

9. APPROVALS:

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