HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of CA15-3 Level		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To illustrate the necessary steps required for performing CA 15-3 assay on COBAS e411

2. DEFINITONS:

2.1 The CA 15-3 values measured are defined using the monoclonal antibodies (MAb) 115D8 and DF3 in a sandwich assay. MAb 115D8 is directed against human milk fat globule membranes, whereas MAb DF3 is directed against the membrane fraction from human metastatic breast cancer.

3. POLICY:

3.1 Immunological in vitro assay for quantitative determination of CA 15-3 in human serum and plasma to aid in the management of breast cancer patients.

3.2 In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid :

3.2.1 In the early detection of recurrence in previously treated stage II and III breast cancer patients.

3.2.2 For monitoring response to therapy in metastatic breast cancer patients.

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-, Na-, NH -heparin and K3-EDTA plasma. Stable for 5 days at 2°-8°C, 3 months at -20°C.

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:** Healthy subjects :(apparently healthy non-pregnant females) <25U/mL.

4.7 **Limitations:** interference:

4.7.1 The assay is unaffected by icterus (bilirubin < 1112 µmol/L or < 65 mg/dL), hemolysis (Hb < 1.9 mmol/L or < 3.0 g/dL), lipemia (Intralipid < 1500 mg/dL) and biotin (< 409 nmol/L or < 100 ng/mL).

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:** 1.00-300 U/mL (defined by the lower detection limit and the maximum of the master curve).

4.8.1 Values below the lower detection limit are reported as < 1.00 U/mL.

4.8.2 Values above the measuring range are reported as > 300 U/mL

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 15-3-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal antibody (115D8; mouse) 1.75 mg/L; phosphate buffer 20 mmol/L, pH 6.0; preservative.

5.1.3 **R2:** Anti-CA 15-3-Ab~Ru (bpy) (black cap), 1 bottle, 10 mL: Monoclonal anti-CA 15-3 antibody (DF3; mouse) labelled with ruthenium complex 10 mg/L; phosphate buffer 100 mmol/L, pH 7.0; 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 analyser 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 analyzer

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 Pericentral Multimarket 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 (or with each run) 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 CA15-3.

6.2 Hormone staff are responsible for running CA15-3samples 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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