HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

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

1.1 To illustrate the necessary steps required for performing CEA assay on COBAS e411.

2. DEFINITIONS:

2.1 Carcinoembryonic antigen (CEA) is a highly glycosylated molecule with a molecular weight of approximately 180 kDa. CEA, like AFP, belongs to the group of carcino-fetal antigens that are produced during the embryonic and foetal period. CEA has been postulated to play a role in several biological processes including cell adhesion, immunity and apoptosis.

3. POLICY:

3.1 The formation of CEA is suppressed after birth and shows a low expression in normal adult tissues. Therefore, only very low CEA levels in the blood of healthy adults can be observed.
3.2 High CEA concentrations are frequently found in cases of colorectal adenocarcinoma.
3.3 Slight to moderate CEA elevations can also occur in non–malignant diseases of the intestine, the pancreas, the liver, and the lungs (i.e. liver cirrhosis, chronic hepatitis, pancreatitis, ulcerative colitis, Crohn's Disease).
3.4 Smoking can also lead to elevated CEA values and needs to be considered when interpreting CEA levels.
3.5 CEA determinations are not recommended for cancer–screening in the general population and CEA concentrations within the normal range do not exclude the possible presence of a malignant Disease.
3.6 The main indication for CEA determinations is to monitor colorectal carcinoma treatment, to identify recurrences after treatment or surgical resection and to aid in staging and assessing metastasis.

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.
  4.2.1 Li-heparin, K2-EDTA and K3-EDTA plasma. Plasma tubes containing separating gel can be used.
  4.2.2 Stable for 7 days at 20°-25°C, 14 days at 2°-8°C, 6 months at -20°C (± 5°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 mIU/ml
4.5 **Status:** Stat and Routine
4.6 **Reference ranges:**
  4.6.1 All subjects <5 ng/mL
  4.6.2 Non-smokers (past/never smokers) <3.8 ng/mL
  4.6.3 Smokers (current)<6.5 ng/mL
4.7 **Limitations- interference:**
  4.7.1 Stable for 7 days at 20°-25 °C, 14 days at 2°-8 °C, 6 months at -20 °C (± 5 °C).
  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:** 0.200-1000 ng/mL

4.8.1 Lower detection limit is reported as < 0.200 ng/mL. Values above the measuring range are reported as > 1000 ng/mL (or up to 50000 ng/mL for 50-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-CEA-Ab~biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-CEA antibody (mouse/human) 3.0 mg/L; phosphate buffer 100 mmol/L, pH 6.0; preservative.

5.1.3 **R2:** Anti-CEA-Ab~Ru(bpy) (black cap), 1 bottle, 8 mL: Monoclonal anti-CEA antibody (mouse) labeled with ruthenium complex 4.0 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 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 PreciControl Tumor Marker or PreciControl Universal. 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 CEA.

6.2 Hormone staff are responsible for running CEA 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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