Title: CORTISOL STIMULATION TEST – ONE HOUR - ADULT

Principle:

The administration of ACTH as cosyntropin (1-24 corticotropin) to normal subjects results in a rapid rise in the serum cortisol level. Patients with adrenal destruction (Addison disease) show no change in serum cortisol level after ACTH administration. Patients with severe atrophy of the adrenal cortex due to glucocorticoid treatment or dysfunction of the pituitary gland or hypothalamus may show a slight rise in the serum cortisol level but not one of normal magnitude.

The procedure requires coordinated interaction between the Phlebotomist and Pathology Resident/Attending (see below).

Specimen Required:

Three serum specimens are drawn at time “zero” (pre-ACTH administration), at 30 minutes and at 60 minutes. The basal or zero time specimen should be collected before 10:00 am and the patient should remain in the out patient waiting area at rest or, if an inpatient, in bed until the test is completed. An AM or PM cortisol draw on the same patient cannot be used for the baseline unless the ACTH is administered with 1 hour of the draw.

Materials and Supplies:

1. Cortrosyn (cosyntropin) for injection 0.25 mg as a sterile lyophilized powder (MAC Lab personnel obtain from the Pharmacy)
2. 5.0 ml ampule of sterile saline for reconstitution of Cortrosyn and flushing of intravenous line
3. Two 2.0 ml sterile syringes with needle
4. Winged infusion set (butterfly) 23 g x ¾ inches
5. SST Tubes - Specimens should be collected into serum separator tubes (green top tubes are not allowed)

Procedure:

1. PHLEBOTOMIST calls the Pathology Resident (2570) or Dr. Flynn (2567) after Cortrosyn vial has been procured from the Pharmacy. NOTE: if patient presents BEFORE 8:00 am, or AFTER 5:00 pm, page on-duty pathology resident (consult BMC switchboard, extension 2000, if necessary to determine which resident is on duty).
PRE-PROCEDURE DISCUSSION WITH PATIENT:

2. **RESIDENT** explains the reason the patient is undergoing ACTH stimulation test and asks if there are any questions.

3. **RESIDENT** asks patient for list of his/her medications and asks whether the patient has ever had an adverse reaction to previous ACTH injection*. If the patient did not bring a list, compile one on the back of a copy of the lab order sheet. The Resident will bring the medication list to Dr. Flynn at the conclusion of the procedure.* (NOTE: the Cortrosyn product insert lists NO medications as interacting with ACTH, and lists history of previous adverse reaction to ACTH injection as the only contraindication to ACTH injection).

4. If the patient admits to having had a previous adverse reaction to Cortrosyn (ACTH) injection, the resident will
   a. obtain additional information from the patient as to details of the event (when, where, what happened);
   b. immediately contact the ordering physician (see end of procedure for contact numbers) and attending pathologist (if not already present) to discuss the issue;
   c. document the conversation on the requisition form (including name of provider and supervising attending pathologist, conclusion of the discussion, and time/date discussed);
   d. **ABORT THE PROCEDURE**;
   e. provide a copy of the requisition form with the above details to Dr. Flynn in the Laboratory for filing.

PREPARATION OF SYRINGE SOLUTIONS (RESIDENT):

5. Using sterile technique and a 2.0 ml syringe and needle, **RESIDENT** draws 1 cc saline into the syringe, and injects it into the Cortrosyn bottle (0.25 mg vial of lyophilized Cortrosyn). Invert mixture in vial back and forth for 10-20 seconds.

6. Using same sterile syringe used for reconstitution, **RESIDENT** pulls back 1 cc of air and pushes air into Cortrosyn bottle. Fill syringe with exactly 1cc of solution. Make sure there are NO AIR BUBBLES. Discard the needle into sharps container. Place the syringe onto the absorbent pad and label syringe “ACTH”.

7. Using a new syringe and a needle with a sterile technique, **RESIDENT** draws up 2 ml sterile saline, expresses air, removes needle and disposes in sharps container, labels syringe “SALINE” and places it onto absorbent pad. USE GREAT CARE NOT TO CONFUSE THE TWO SYRINGES.
VENIPUNCTURE (PHLEBOTOMIST):

8. Using sterile technique, **PHLEBOTOMIST** performs venipuncture with the butterfly.

9. **PHLEBOTOMIST** draws a baseline serum specimen. Label “baseline”. Baseline draw should be **no more than** 30 to 60 minutes prior to injection of ACTH.

10. **PHLEBOTOMIST** removes tourniquet.

11. Using paper tape, **PHLEBOTOMIST** places tape over butterfly assembly to anchor it to the arm.

INJECTION (RESIDENT):

12. **RESIDENT** removes any residual air from the ACTH syringe, making sure that there is exactly 1cc of ACTH solution, attaches syringe to butterfly and injects into patient **SLOWLY**.

13. **RESIDENT** attaches SALINE syringe to butterfly (first ensuring that any residual air is removed from syringe). Inject saline SLOWLY. This procedure flushes any Cortrosyn remaining in the butterfly tubing into the patient.

14. **RESIDENT** observes patient for signs of allergic reaction (anaphylaxis) – refer to Addendum 1 below. Contact attending pathologist (Dr. Flynn, or other pathologist in his absence) IMMEDIATELY for signs of adverse reaction (including suspected vaso-vagal episode).

PHLEBOTOMIST:

15. Write the **EXACT TIME** of collection and initials of the person who collected the specimen on the blood tube. Allow blood to clot and spin tube to separate serum from cells. Tube may be held at room temperature until all tubes are collected.

16. In exactly 30 minutes, collect a serum sample and label tube “30 minutes”.

17. At exactly 60 minutes, collect a serum sample and label tube “60 minutes”.

18. Send the baseline serum, 30 minute and 60 minute serum specimens to the lab for cortisol determinations.
19. NOTE: contact the Pathology Resident (2570) or Dr. Flynn (2567) IMMEDIATELY for any suspected adverse reaction to Cortrosyn. (Allergic reaction will generally occur in the first few minutes after Cortrosyn injection.)

**POST-PROCEDURE (Resident):**

20. Provide Dr. Flynn with a list of the patient’s medications for record retention.*

21. Enter the encounter into the Clinical Consult Excel file (accessible at \Bhshlp\dfsroot\BHS_PathologyResidents.dd\CLINICAL CALL LOG)

**Expected Values:**

Normally serum cortisol will increase by greater than 7 ug/dL with a peak serum cortisol greater than 20 ug/dL. Note that the peak value is more important than the incremental change since an incremental change may be absent in stressed patients where adrenal output of cortisol is already maximally stimulated by endogenous ACTH.

**NOTE:**

*When receiving specimen* into the lab computer, the exact collection times for each specimen must be entered.

* JCAHO requirement NPSG.08.01.01: A process must exist for comparing the patient’s current medications with those ordered for the patient while under the care of BMC.
CORTROSYN™ (cosyntropin) for injection exhibits slight immunologic activity, does not contain animal protein and is therefore less risky to use than natural ACTH. Patients known to be sensitized to natural ACTH with markedly positive skin tests will, with few exceptions, react negatively when tested intradermally with CORTROSYN™. Most patients with a history of a previous hypersensitivity reaction to natural ACTH or a pre-existing allergic disease will tolerate CORTROSYN™. Despite this however, CORTROSYN™ is not completely devoid of immunologic activity and hypersensitivity reactions including rare anaphylaxis are possible. Therefore, the physician should be prepared, prior to injection, to treat any possible acute hypersensitivity reaction.

A rare hypersensitivity reaction usually associated with a pre-existing allergic disease and/or a previous reaction to natural ACTH is possible. Symptoms may include slight whealing with splotchy erythema at the injection site. There have been rare reports of anaphylactic reaction. The following adverse reactions have been reported in patients after the administration of CORTROSYN™ and the association has been neither confirmed nor refuted:

a. bradycardia  
b. tachycardia  
c. hypertension  
d. peripheral edema  
e. rash