

## Special Communication

Date: 2/2/17

Dear Client:

We are writing to inform you of upcoming changes to six tests in our directory: **MALIGG, FLT3MD, FLUOX, EHISTO, PBALIN, and CKISO.**

Please accept our apologies for any inconvenience this change in testing may have caused. If you have any medical questions, please contact Thomas Daly, MD at [dalyt@ccf.org](mailto:dalyt@ccf.org) or 216.444.4547. If you have other questions about this change, please contact Laboratory Client Services at 800.628.6816, and one of our representatives will be happy to assist you.

Sincerely,



Donna D. Cooper, MS, MBA  
Manager of Laboratory Client Services and Test Utilization

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### **Test: Malaria Antibody, IgG (MALIGG)**

Effective immediately, Malaria Antibody, IgG (MALIGG) testing has been discontinued. Any new information regarding this test will be communicated in a future *Technical Update*.

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### **Test: FLT3 Mutation Detection by PCR (FLT3MD)**

Effective 2/6/17, FLT3 Mutation Detection by PCR (FLT3MD) will include the following changes:

#### **Special Information**

**Must indicate specimen type. Unacceptable conditions: Grossly hemolyzed or clotted specimens. This test is New York DOH approved.**

#### **Specimen Requirement**

The primary specimen will still be 5 mL whole blood in an EDTA lavender tube; however the minimum volume will increase to **5 mL**. Minimum volumes will increase for the alternate samples as well. The alternate samples include 5 mL whole blood in a sodium or lithium heparin green top tube OR ACD A or B (yellow) tube; Minimum volume **5 mL**, 3 mL bone marrow in an ACD A or B (yellow) tube OR EDTA lavender tube OR sodium or lithium heparin green top tube; Minimum volume **3 mL**. **Also acceptable is 1 µg extracted DNA; Minimum volume 1 µg.** Transport temperature is refrigerated.



### **Stability**

Ambient: **72 hours**

Refrigerated: 1 week for blood and bone marrow; **indefinitely for extracted DNA**

Frozen: Unacceptable

### **Days Performed and Reported**

Days performed varies, but reporting time will be **5 – 12 days**.

### **CPT**

81245 x 1, 81246 x 1

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## **Test: Fluoxetine/Norfluoxetine**

Effective 2/6/17, Fluoxetine/Norfluoxetine (FLUOX) will include the following changes:

### **Special Information**

**Unacceptable conditions: Separator tubes. This test is New York DOH approved.**

### **Clinical Information**

**Optimize drug therapy and monitor patient adherence.**

### **Specimen Requirement**

Specimen volume requirements are increasing for this test. The primary specimen will be **3 mL** serum from a red top tube with no additive; Minimum volume **1.2 mL**. **Draw 2 tubes to ensure adequate specimen volume.** Do not use serum separator tubes. Separate serum from cells **ASAP** or within 2 hours of collection **and transfer to aliquot tube**. The alternate specimen will be **3 mL** plasma from an EDTA lavender top tube; Minimum volume **1.2 mL**. **Draw 2 tubes to ensure adequate specimen volume.** Do not use plasma separator tubes. Separate plasma from cells **ASAP** or within 2 hours of collection **and transfer to aliquot tube**.

### **Stability**

Ambient: **1 week**

Refrigerated: **2 weeks**

Frozen: **18 months**

### **Methodology**

**Gas Chromatography Mass Spectrometry (GCMS)**

### **Reference Range**

Fluoxetine: **Refer to report**

Norfluoxetine: **Refer to report**

### **Days Performed and Reported**

Days performed **varies**, and reporting time will be **5 – 12 days**.



### Price

Price will increase to **\$138.00 (non-discountable)**.

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### **Test: Entamoeba histolytica, IgG (EHISTO)**

Effective 2/6/17, Entamoeba histolytica, IgG (EHISTO) will include the following changes:

#### Special Information

Acute and convalescent specimens must be labeled as such; parallel testing is preferred and convalescent specimens **MUST** be received within 30 days from receipt of the acute specimens. **Unacceptable conditions: Contaminated, heat-inactivated, hemolyzed or severely lipemic specimens. This test is New York DOH approved.**

#### Clinical Information

**Aid in the detection of amebic liver abscess. Test is not useful for intestinal infection.** In case of extraintestinal complications, a positive antibody can indicate amebiasis even though stool findings are negative. Seroconversion between acute and convalescent sera is considered strong evidence of recent infection. The best evidence for infection is a significant change on two appropriately timed specimens where both tests are done in the same laboratory at the same time.

#### Specimen Requirement

The primary specimen will still be 1 mL serum from a serum separator (gold) tube. The minimum volume is decreasing to **0.1 mL**. Separate serum from cells ASAP or within 2 hours of collection. Please mark specimen plainly as ACUTE or CONVALESCENT. Transport temperature is refrigerated.

#### Reference Range

Negative: **No significant level of detectable E. histolytica IgG Antibody: 8 U or less**  
Equivocal: (Repeat testing in 10-14 days **may be helpful**) **9 - 11 U**  
Positive: (Current or past infection) **12 U or greater**

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### **Test: Pregabalin (PBALIN)**

Effective 3/1/2017, Pregabalin (PBALIN) will include the following changes:

#### Special Information

**This test is New York State approved.**

#### Specimen Requirement

The primary specimen will still be 1 mL serum from a red top tube with no additive. The minimum volume requirement will decrease to **0.5 mL**. **Draw specimen immediately before next scheduled dose. Centrifuge within 2 hours of draw and transfer to plastic vial.** Do not use serum separator tubes.

**Stability**

Ambient: **28 days**

Refrigerated: **28 days**

Frozen: **28 days**

**Reference Range**

**2.0 – 5.0 mcg/mL**

**Days Performed and Reported**

Days performed will still be daily, but reporting time will be **2 – 3 days**.

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**Test: CK Isoenzymes (CKISO)**

Effective 3/6/2017, CK Isoenzymes (CKISO) will include the following changes:

**Includes**

% CKBB

% CKMB

% CKMM

Creatine Kinase, Total

**Interpretation**

**Special Information**

Hemolyzed specimens will be rejected. **Specimens received thawed will be rejected.** CK-MB and CK-BB are temperature labile. Repeated freeze/thaw cycles destroy CK activity. If CK and CK Isoenzymes are ordered together, specimen must be submitted frozen.

**Specimen Requirement**

The primary specimen will still be 2 mL serum in a serum separator (gold) tube. Minimum volume is 1 mL. The change is the removal of the alternate specimen, a red top tube with no additive.

**Stability**

Ambient: Unacceptable

Refrigerated: **48 hours**

Frozen: **14 days**