



## **Division of Survey and Certification, Region VI**

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June 3, 2019

Elisabeth Wagar, MD, Laboratory Director  
UT MD Anderson Clinical Lab  
1515 Holcomb BLVD  
Houston, TX 77030

**Reference**                      **CLIA No. 45D0491588: Complaint Investigation Survey Findings**  
**Condition Level Non-Compliance**

Dear Dr. Wagar:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, and bill for services provided to Medicare beneficiaries or Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA Requirements (42 CFR 493). Federal regulations authorize surveys to determine whether a laboratory complies with the applicable CLIA regulations.

### **Temporary Removal of Deemed Status:**

Section 353(e) of the Public Health Service Act (PHSA) and implementing regulations provide that a laboratory accredited by an approved accreditation organization will be deemed to meet the conditions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Centers for Medicare & Medicaid Services (CMS) deem laboratories accredited by The College of American Pathologists (CAP) to meet CLIA Conditions. 42 CFR Part 493, Subpart E, requires CMS or its agent to conduct surveys on a representative sample of accredited laboratories or in response to a substantial allegation of noncompliance. If, in the course of such a survey, a laboratory is found to not be in compliance with applicable CLIA Conditions, CMS will monitor the correction of any deficiencies until such time compliance is achieved or the certificate of accreditation is revoked. Until the laboratory is back in compliance it will be under the jurisdiction of CMS and not CAP.

### **Survey Findings:**

The Texas Health and Human Services Commission (THHSC) conducted a complaint investigation survey of your laboratory **March 29 – April 5, 2019**. THHSC notified your staff at the exit conference that your laboratory demonstrated condition level noncompliance with the conditions required for participating in the CLIA program. The survey and sanction recommendations were forwarded to the Centers for Medicare & Medicaid Services (CMS). CMS has reviewed the survey report and concurred with the survey findings of condition level noncompliance. A complete listing of all deficiencies is enclosed in the CMS Form 2567.

Specifically, your laboratory did not meet the following CLIA Condition(s):

- 42 CFR § 493.1101 Condition: Facility Administration;
- 42 CFR § 493.1217 Condition: Immunohematology;
- 42 CFR § 493.1230 Condition: General Laboratory Systems;
- 42 CFR § 493.1441 Condition: Laboratory Director, high complexity testing
- 42 CFR § 493.1447 Condition: Technical Supervisor, high complexity testing; and
- 42 CFR § 493.1487 Condition: Personnel, High complexity testing

Submission of the Plan of Correction (POC) and Allegation of Compliance (AOC):

By **June 18, 2019**, the laboratory must submit a plan of correction (POC) to the THHSC, with copies to CMS, for the deficiencies cited on the enclosed CMS-2567. The laboratory may use a word document to prepare the plan of correction. Please indicate the specific citation-Dtag along with a correction date for each citation –Dtag. **The laboratory director must sign, date the first page of the CMS-2567 and the attached word document. Please return the completed CMS-2567 to CMS and THHSC.** Please retain a copy for your files.

An acceptable plan of correction (POC) must include:

- **How** the deficient practice will be corrected or how it has been corrected;
- **When** the corrective action(s) will be completed (date) or when corrected;
- **What** corrective actions(s) have been taken for patients found to have been affected by the deficient practice;
- **Who** will be responsible for implementing the corrections;
- **How** the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- **What** measure(s) has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and
- **How** the corrective action(s) is being monitored to ensure the deficient practice does not recur and who is monitoring the corrections.

Also by **June 18, 2019**, the laboratory must submit a credible allegation of compliance (AOC) to the THHSC with copies to CMS, in order to demonstrate that actions taken by the lab have addressed the condition level deficiencies cited on the CMS-2567.

A credible AOC is a statement and documentation:

- **Made** by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required; and
- That is **realistic** in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- That **indicates the removal** and resolution of Condition level deficiencies

The AOC may be submitted as a separate document from the POC along with the supporting evidence. Please submit the AOC and POC to this office as well as a copy to the THHSC at the following address:

ATTN: Jennifer Berger, B.S., MT (ASCP);  
 CLIA Inspector - Houston Group  
 Health Care Quality Section  
 Texas Health and Human Services Commission  
 Phone: 713-767-3340  
 Fax: 713-767-3367  
[jennifer.berger@hhsc.state.tx.us](mailto:jennifer.berger@hhsc.state.tx.us)

THHSC must receive your credible allocation (AOC) and your plan of correction (POC) in order for a revisit to be scheduled. If an acceptable AOC/POC is not received, THHSC cannot schedule a revisit to ensure corrections and CLIA compliance. CMS does have the authority to impose sanctions.

**Contact Information:**

If you have any questions about the administrative aspects of this enforcement, please contact CAPT Daniel Hesselgesser, MT (ASCP) at [daniel.hesselgesser@cms.hhs.gov](mailto:daniel.hesselgesser@cms.hhs.gov) or (214) 767-5570. If you have questions about the technical/clinical aspects of this enforcement please contact Jennifer Berger at [jennifer.berger@hhsc.state.tx.us](mailto:jennifer.berger@hhsc.state.tx.us) or (713)767-3340.

Sincerely,

James L. Dickens, Manager  
Survey Branch

Enclosures: Statement of Deficiencies, form CMS-2567

cc: THHSC

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