

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0926410	<b>(X3) Date Survey Completed</b>  02/17/2022
<b>Name of Provider or Supplier</b>  North Houston Medicine, Tumor & Blood Clinic, Pa	<b>Street Address, City, State</b>  1631 North Loop West, #100, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification records and staff interview, it was revealed that the laboratory failed to have documentation of verifying its patient normal range for complete blood count (CBC) testing on the Cell-Dyn Emerald hematology analyzer. Findings include: 1. A review of the laboratory's verification records for the Cell-Dyn Emerald hematology analyzer (Serial number 030717-</p>

007201) revealed verification studies were performed in June 2021. 2. The laboratory was asked to provide documentation of verifying the following patient normal ranges for CBC testing on the Cell-Dyn Emerald hematology analyzer. No documentation was provided. 3. An interview with the technical consultant on 2/17/22 at 10:20 a.m. in the laboratory, after review of the records, confirmed the above findings.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to specify in writing the responsibilities and duties for 1 of 1 technical consultant. Findings include: 1. A review of the laboratory's submitted CMS 209 form identified one technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory director failed to have written responsibilities and duties for the technical consultant. 3. An interview with the technical consultant on 2/17/22 at 9:46 a.m. in the laboratory, after review of the records, confirmed the above findings.