

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0926410	<b>(X3) Date Survey Completed</b>  11/13/2019
<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>The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.</p>
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing records, and confirmed in interviewed, the laboratory failed to test the proficiency testing material the same as patient samples for the CBC (complete blood count) testing on the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Proficiency Testing - Guidelines revealed "all samples are to be tested in the same manner as routine clinical materials." 2. Review of the 2019 API 1st event proficiency testing records revealed the laboratory testing person analyzed the PT samples two times, then cleaned [performed maintenance] the</p>

analyzer, then reanalyzed the PT samples two more times. Records revealed 4 instrument printouts for each PT sample. 3. An interview with the primary testing person on 11/13/19 at 1050 hours in the laboratory confirmed that the laboratory does not perform patient samples twice, then perform maintenance, then reanalyze specimens.

**D2016**

**SUCCESSFUL PARTICIPATION**  
CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:  
Based on review of proficiency testing records and interview of facility personnel, the laboratory failed to successfully participate in a proficiency testing program for the specialty of routine hematology for Cell ID (White blood cell differential). Refer to D2130

**D2121**

**HEMATOLOGY**  
CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:  
Based on review of the 2019 American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to obtain at least 80% for the hematology analyte: RBC (red blood cells) and Cell ID (white blood cell differential). Findings were: 1. Review of the API 2019 proficiency testing records revealed documentation the laboratory failed to obtain at least 80% for the following analytes: 2019 API 2nd event Cell ID - 27% Granulocytes - 0% Hem-06: 68.3 (acceptable range 57.7-63.7) Hem-07: 70.2 (acceptable range 60.6 - 64.9) Hem-08: 82.7 (acceptable range 73.7 - 78.4) Hem-09: 80.1 (acceptable range 68.0 - 74.0) Hem-10: 45.0 (acceptable range 32.6 - 41.7) Lymphocytes - 20% Hem-06: 21.1 (acceptable range 25.2 - 34.8) Hem-07: 23.0 (acceptable range 24.8 - 31.4) Hem-08: 12.5 (acceptable range 12.9 - 18.1) Hem-10: 45.3 (acceptable range 47.4 - 60.3) Monocytes - 60 % Hem-08: 4.8 (acceptable range 6.8 - 10.0) Hem-09: 6.4 (acceptable range 11.1

- 14.7) RBC - 40% Hem-06: 3.97 (acceptable range 3.98 - 4.50) Hem-07: 3.52 (acceptable range 3.57 - 4.04) Hem-10: 2.12 (acceptable range 2.18 - 2.46) 2019 API 1st event Cell ID - 13% Granulocytes - 0% Hem-01: 71.4 (acceptable range 59.3 - 64.7) Hem-02: 45.4 (acceptable range 32.9 - 42.2) Hem-03: 83.1 (acceptable range 72.0 - 78.1) Hem-04: 69.3 (acceptable range 57.2 - 64.0) Hem-05: 78.9 (acceptable range 61.4 - 71.1) Lymphocytes - 20% Hem-01: 23.5 (acceptable range 25.2 - 30.3) Hem-03: 12.7 (acceptable range 13.0 - 18.3) Hem-04: 25.9 (acceptable range 27.0 - 33.5) Hem-05: 14.0 (acceptable range 14.4 - 18.7) Monocytes - 20% Hem-01: 5.1 (acceptable range 8.6 - 11.9) Hem-03: 4.2 (acceptable range 7.7 - 10.6) Hem-04: 4.8 (acceptable range 7.0 - 11.3) Hem-05: 7.1 (acceptable range 13.8 - 20.4) 2. An interview with the primary testing person on 11/13/19 at 1105 in the laboratory confirmed the above findings.

**D2122**

HEMATOLOGY  
CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory American Proficiency Institute (API) proficiency testing records from 2019 and interview of facility personnel, the laboratory failed to attain an overall testing event score of at least 80 % for each event which constitutes unsatisfactory performance. Findings were: 1. A review of the 2019 API proficiency testing revealed a hematology event score of less than 80% (unsatisfactory performance) for the API 2nd event (77%). 2. An interview with the primary testing person on 11/13/19 at 1050 hours in the laboratory confirmed the above findings.

**D2128**

HEMATOLOGY  
CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policy, American Proficiency Institute (API) proficiency testing records, PT corrective actions, and confirmed in interview, the laboratory failed to document the remedial action for 2 of 2 hematology testing events with PT failures. Findings were: 1. Review of the laboratory policy Proficiency Testing - Guidelines revealed "corrective actions is required when an incorrect response is obtained; a test result is undgraded due to no consensus; a test result returns with an overall score less than 80%. If the repeat proficiency analyte test result is incorrect, the site coordinator must initiate and document corrective action." 2. Review of the 2019 1st and 2nd event API proficiency testing records revealed no documentation of the patient remedial action for both test events with PT failures. 2019 API 2nd event Cell ID - 27% Granulocytes - 0% Hem-06: 68.3 (acceptable

range 57.7-63.7) Hem-07: 70.2 (acceptable range 60.6 - 64.9) Hem-08: 82.7 (acceptable range 73.7 - 78.4) Hem-09: 80.1 (acceptable range 68.0 - 74.0) Hem-10: 45.0 (acceptable range 32.6 - 41.7) Lymphocytes - 20% Hem-06: 21.1 (acceptable range 25.2 - 34.8) Hem-07: 23.0 (acceptable range 24.8 - 31.4) Hem-08: 12.5 (acceptable range 12.9 - 18.1) Hem-10: 45.3 (acceptable range 47.4 - 60.3) Monocytes - 60 % Hem-08: 4.8 (acceptable range 6.8 - 10.0) Hem-09: 6.4 (acceptable range 11.1 - 14.7) RBC - 40% Hem-06: 3.97 (acceptable range 3.98 - 4.50) Hem-07: 3.52 (acceptable range 3.57 - 4.04) Hem-10: 2.12 (acceptable range 2.18 - 2.46) 2019 API 1st event Cell ID - 13% Granulocytes - 0% Hem-01: 71.4 (acceptable range 59.3 - 64.7) Hem-02: 45.4 (acceptable range 32.9 - 42.2) Hem-03: 83.1 (acceptable range 72.0 - 78.1) Hem-04: 69.3 (acceptable range 57.2 - 64.0) Hem-05: 78.9 (acceptable range 61.4 - 71.1) Lymphocytes - 20% Hem-01: 23.5 (acceptable range 25.2 - 30.3) Hem-03: 12.7 (acceptable range 13.0 - 18.3) Hem-04: 25.9 (acceptable range 27.0 - 33.5) Hem-05: 14.0 (acceptable range 14.4 - 18.7) Monocytes - 20% Hem-01: 5.1 (acceptable range 8.6 - 11.9) Hem-03: 4.2 (acceptable range 7.7 - 10.6) Hem-04: 4.8 (acceptable range 7.0 - 11.3) Hem-05: 7.1 (acceptable range 13.8 - 20.4) 3. An interview with the primary testing person on 11/13/19 at 1110 hours in the laboratory confirmed the above findings.

**D2130**

**HEMATOLOGY**  
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing (PT) records from 2018 and 2019, and confirmed in interview, the laboratory failed to attain a satisfactory performance (score of at least 80 %) for 2 of 3 events for Cell ID (White blood cell differential). Findings were: 1. Review of the 2018 - 2019 API proficiency testing records revealed 2 of 3 consecutive events when the laboratory failed to attain at least an 80% score for Cell ID. API 2019 1st event Cell ID 13% API 2019 2nd event Cell ID 27% 2. An interview with the primary testing person on 11/13 /19 at 1050 hours in the laboratory confirmed the above findings.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to document the review of the PT results for all 2019 test events. The findings were: 1. A review of the laboratory's 2019 API proficiency testing records revealed that the laboratory failed to document the review of the results for all events in 2019. 2019 Hematology 1st & 2nd event 2. An interview with the primary testing person on 11/13 /19 at 1040 hours in the laboratory confirmed the above findings.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

A review of the laboratory's policies and procedures, proficiency testing records and confirmed in interview, the laboratory failed to verify the accuracy of the CBC (complete blood count) analyte MPV (mean platelet volume). Findings were: 1. Review of the laboratory policy Proficiency Testing - Guidelines revealed "corrective action is required when a test result is ungraded due to no consensus." 2. A review of the American Proficiency Institute proficiency testing events from 2019 revealed 1 of 2 events when the proficiency testing program did not grade an analyte. Review of the laboratory records revealed no documentation that the laboratory verified the accuracy of their results per the laboratory policy. 2019 1st API event MPV Hem-02: 10.4 Not graded Hem-04: 9.5 Not graded Hem-05: 9.6 Not graded 3. An interview with the primary testing person on 11/13/19 at 1035 hours in the laboratory confirmed the above findings. She was unaware that the laboratory was required to verify ungraded results.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the 2019 American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to obtain at least 80% for the analyte RDW (Red blood cell distribution width). Findings were: 1. Review of the laboratory 2019 API proficiency testing records revealed the laboratory failed to obtain at least an 80% for RDW. 2019 API 2nd event RDW - 20% Hem-06: 15.1 (acceptable range 17.0 - 21.7) Hem-07: 16.6 (acceptable range 17.3 - 21.9) Hem-08: 14.3 (acceptable range 15.5 - 19.4) Hem-09: 15.1 (acceptable range 15.8 - 19.6) 2019 API 1st event RDW - 0% Hem-01: 17.1 (acceptable range 18.2 - 22.3) Hem-02: 17.1 (acceptable range 17.9 - 23.5) Hem-03: 14.7 (acceptable range 16.4 - 20.2) Hem-04: 17.2 (acceptable range 17.6 - 22.0) Hem-05: 16.3 (acceptable range 17.0 - 20.8) 2. An interview with the primary testing person on 11/13/19 at 1050 hours in the laboratory confirmed the above findings.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test

results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policy, quality control records, patient test records, and confirmed in interview, the laboratory failed to document corrective actions taken when quality control is outside of the acceptable range for CBC (complete blood count) quality control testing on the Cell-Dyn Emerald hematology analyzer. Findings were: 1. Review of the laboratory policy Quality Control Review revealed "if QC is out of limits, the corrective actions for out of limits QC must be followed and documented on the problem log and/or in the lab computer. 2. Random review of the laboratory quality control records from September - November 2019 revealed 6 of 20 days with quality control failures and no documentation of the corrective action. Date QC lot 11/08/19 L9266 11/11/19 L9266 10/10/19 H9182 10/07/19 L9182 09/09/19 L9182 09/03/19 L9182 3. Review of the patient test records from the above dates revealed the laboratory performed patient testing. Date Patient 11/08/19 8002, 4730, 1945 11/11/19 1960, 0199, 4644 10/10/19 7065, 4342, 7280 10/07/19 6051, 0809, 6519 09/09/19 3503, 0209, 6962 09/03/19 0223, 7065, 8889 4. An interview with the primary testing person on 11/13/19 at 1105 hours in the laboratory confirmed the above findings.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of laboratory API proficiency testing records and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016, D6019

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of API proficiency testing results and confirmed in interview, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2130

<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's API proficiency testing records and confirmed in interview, the laboratory director failed to ensure that an approved correction plan was followed when any proficiency testing were found unsatisfactory. (Refer to D2128)</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's proficiency testing records, facility procedures, record review and staff interview, it was revealed that the Technical Consultant failed to provide technical and scientific oversight. (Refer to D6036)</p>
<p><b>D6036</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, instrument printouts, and confirmed in interview, the Technical Consultant failed to provide technical oversight and ensure the laboratory successfully participated in a proficiency testing program for the specialty of routine hematology. Refer to D2130</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, personnel records and confirmed in interview, the technical consultant (TC) failed to document annual competency for 3 of 3 testing</p>

persons performing moderate complexity testing. Findings included: 1. Review of the laboratory policy Competency of Personnel revealed "all employees are assessed for competency through the use of the orientation/skills assessment check list. The skills assessment tool lists the primary job functions to be performed in a competent manner. For testing personnel, unknowns and/or proficiency survey samples are tested and the results compared to the expected values. A satisfactory assessment is required for all employees annually. 2. Review of the 2018 and 2019 competency assessments revealed no documentation of competencies for 3 of 3 testing personnel. 3 An interview with the lab director (who is also the technical consultant) on 11/13/19 at 1035 hours in the laboratory confirmed the above findings.