

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0966458	<b>(X3) Date Survey Completed</b> 03/16/2022
<b>Name of Provider or Supplier</b> Uthealth East Texas Hope Cancer Center	<b>Street Address, City, State</b> 115 Medical Circle Suite 106, Athens, 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>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of competency records from 2020 to 2021 and confirmed in interview found the laboratory failed to document competency assessment for 1 of 2 technical consultant (TC). The findings were: 1. Review of laboratory competency records from 2020 to 2021 revealed there was no competency assessments for TC#2. 2. An interview with TC#2 on 3/16/2022 at 10:00 am in the office confirmed that there was no competency assessment documented for TC#2. Key: TC= Technical consultant</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in</p>

electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on the review of manufacturer's instructions for use, the laboratory's temperature log from 2021, and confirmed in an interview found the laboratory failed to follow the manufacturer's instructions of relative humidity for eight of 50 days reviewed for 1 of 1 instrument: Sysmex XS-1000i hematology instrument. The findings were: 1. Review of the manufacturer's instruction for use, XS-1000i/XS-800i instruction for use (Code#: 461-2629-2; Printed in Japan; Date of last revision: June 2013) on page 11-1 11.3 XS-1000i/XS-800i performance /specifications revealed the relative humidity is 30% to 85%. 2. Review of the laboratory's temperature log revealed the acceptable ranges for humidity was 20% to 85%. 3. Further review of the laboratory's temperature log from 2021 revealed eight of 50 days reviewed were out of acceptable range for Sysmex XS-1000i (SN#: 75408). 1/11/21 27% 1/12/21 27% 1/13/21 28% 1/15/21 25% 1/28/21 29% 1/29/21 29% 3/08/21 26% 4/02/21 27% 3. Random review of the patient results for the above dates revealed the following patient testing on Sysmex XS-1000i (SN#: 75408). 1/11/21 Patient ID: 2054471 1/11/21 Patient ID: 1028075 1/11/21 Patient ID: 1024618 1/11/21 Patient ID: 2054055 1/11/21 Patient ID: 2042564 1/12/21 Patient ID: 2054302 1/12/21 Patient ID: 2052762 1/12/21 Patient ID: 2029754 1/12/21 Patient ID: 2041953 1/12/21 Patient ID: 2052066 1/13/21 Patient ID: 2034574 1/13/21 Patient ID: 2053658 1/13/21 Patient ID: 2045725 1/13/21 Patient ID: 2053552 1/13/21 Patient ID: 2030312 1/15/21 Patient ID: 2054500 1/15/21 Patient ID: 2053039 1/15/21 Patient ID: 2029529 1/15/21 Patient ID: 2046289 1/15/21 Patient ID: 2051684 1/28/21 Patient ID: 2051912 1/28/21 Patient ID: 2032799 1/28/21 Patient ID: 2025145 1/28/21 Patient ID: 2044426 1/28/21 Patient ID: 2054633 1/29/21 Patient ID: 2054000 1/29/21 Patient ID: 2037785 1/29/21 Patient ID: 2036760 1/29/21 Patient ID: 2053491 1/29/21 Patient ID: 2046289 3/08/21 Sample ID: 000501008 3/08/21 Sample ID: 000501009 3/08/21 Sample ID: 000501010 3/08/21 Sample ID: 000501013 4/02/21 Sample ID: 000504289 4/02/21 Sample ID: 000504288 4/02/21 Sample ID: 000504293 4/02/21 Sample ID: 000504313 4/02/21 Sample ID: 000504332 4. An interview with the technical consultant #2 on 3/16/22 at 1:00 pm in the office confirmed the above findings.

**D5461**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(6)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the review of manufacturer's instructions for use, the laboratory reagent replacement log from 4/15/21 to 3/15/22, and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent on one of one Sysmex XS1000i hematology instrument for eight of 30 days reviewed. The findings were: 1. Review of the manufacturer's instruction for use, XS-1000i/XS-800i instruction for use (Code#: 461-2629-2; Printed in Japan; Date of last revision: June

2013) in Chapter 4 revealed the XS-1000i uses the following four reagents. Cellpack Stromatolyser-4DL Stromatolyser-4DS Sulfolyser 2. Random review of the reagent replacement log from 4/15/21 to 3/15/22 revealed eight of 30 days reviewed with no documentation of the quality control run after the following reagent change on the Sysmex XS-1000i (SN#75408) hematology analyzer. 05/05/21 at 9:54 am Cellpack Lot#Y1019 Exp 8/22/22 05/21/21 at 8:52 am Sulfolyser Lot#Y1001 Exp 12/31/21 07/22/21 at 2:02 pm Cellpack Lot#Y1005 Exp 7/12/22 08/26/21 at 9:56 am Stromatolyser-4DS Lot#Y1006 Exp 2/25/22 10/05/21 at 12:47 pm Sulfolyser Lot#Y1005 Exp 5/23/22 11/10/21 at 1:39 pm Cellpack Lot#Y1075 Exp 1/18/23 12/08/21 at 8:55 am Stromatolyser-4DS Lot#Y1012 Exp 4/18/22 03/10/22 at 10:11 am Cellpack Lot#Y1128 Exp 6/21/23 3. Random review of the patient test records for the above date revealed the laboratory performed the following patient testing after the reagent change above with no documentation of the quality control run. 05/05/21 at 10:14 am Sample ID: 000508165 05/05/21 at 10:50 am Sample ID: 000508177 05/05/21 at 11:53 am Sample ID: 000508198 05/05/21 at 1:33 pm Sample ID: 000508219 05/05/21 at 2:17 pm Sample ID: 000508237 05/21/21 at 9:43 am Sample ID: 000510174 05/21/21 at 11:02 am Sample ID: 000510207 05/21/21 at 2:58 pm Sample ID: 000510257 05/21/21 at 3:20 pm Sample ID: 000510157 07/22/21 at 2:07 pm Sample ID: 000517515 07/22/21 at 2:15 pm Sample ID: 000517519 07/22/21 at 2:22 pm Sample ID: 000517524 07/22/21 at 2:43 pm Sample ID: 000517533 07/22/21 at 2:49 pm Sample ID: 000517511 07/22/21 at 3:03 pm Sample ID: 000517536 08/26/21 at 10:16 am Sample ID: 000521277 08/26/21 at 10:19 am Sample ID: 000521272 08/26/21 at 10:47 am Sample ID: 000521293 08/26/21 at 10:50 am Sample ID: 000521295 08/26/21 at 1:30 pm Sample ID: 000521329 08/26/21 at 2:55 pm Sample ID: 000521357 10/05/21 at 2:06 pm Sample ID: 2023574996 10/05/21 at 2:13 pm Sample ID: 2023575227 10/05/21 at 2:42 pm Sample ID: 2023575949 11/10/21 at 2:11 pm Sample ID: 2024492146 11/10/21 at 2:20 pm Sample ID: 2024492350 11/10/21 at 2:27 pm Sample ID: 2024492550 11/10/21 at 3:00 pm Sample ID: 2024493273 11/10/21 at 3:11 pm Sample ID: 2024493402 12/08/21 at 8:57 am Sample ID: 2025204758 12/08/21 at 9:47 am Sample ID: 2025206757 12/08/21 at 1:10 pm Sample ID: 2025213258 12/08/21 at 1:26 pm Sample ID: 2025213499 12/08/21 at 3:05 pm Sample ID: 2025217781 12/08/21 at 3:41 pm Sample ID: 2025217253 3/10/22 at 10:23 am Sample ID: 2027599465 3/10/22 at 10:44 am Sample ID: 2027599143 3/10/22 at 11:34 am Sample ID: 2027600818 3/10/22 at 1:28 pm Sample ID: 2027605173 3/10/22 at 2:23 pm Sample ID: 2027606486 4. An interview with the TC#2 on 3/16/22 at 10:25 am in the office confirmed the above findings. Key: TC=Technical consultant