| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D2089479 | 07/03/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Uf Health North | 15255 Max Leggett Pkwy, Jacksonville, FL | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2121** | HEMATOLOGY<br>CFR(s): 493.851(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of American Proficiency Institute (API) proficiency testing results and staff interview, the laboratory had 1 out of 3 testing events in 2017 that had an analyte that received less than 80% in the specialty of Hematology. The findings include: Review of API proficiency testing results found the 3rd testing event in 2017 had a 0% for Body Fluid Cell Count which included Red Blood Cells and White blood Cells. During an interview on 7/2/18 at 12:21pm, the Laboratory Quality Manager confirmed the proficiency testing failures. |
| **D2182** | ANTIBODY IDENTIFICATION<br>CFR(s): 493.865(a)<br><br>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of American Proficiency Institute (API) proficiency testing results and staff interview, the laboratory had 1 out of 3 testing events in 2017 and 1 event in 2018 that had an analyte that received less than 80% in the specialty of Antibody Identification. The findings include: Review of API proficiency testing results found the 3rd testing event in 2017 had a 50% for Fetal Screen, and the 1st event of 2018 had a result of 50% for Direct Antiglobulin Test. The interview on 7/2/18 at 12:21pm with the Laboratory Quality Manager confirmed the failures. |

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| **D3021** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(c)(1)<br><br>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the facility failed to ensure the temperatures of Plasma Thawer #1 and #2 were documented in the acceptable range of 36C +/- 1C for two of three months reviewed. (July 2017 and January 2018) The findings include: The record review of the "Plasma Thawer Quality Control" documents for July 2017 showed the following days temperatures of Plasma Thawer #1 were not in range per the policy "Helmer Plasma thawer Routine Operation and Maintenance": 7/12/17 - 37.2C, 7/13/17 - 37.3C, 7/14/17- 37.2C, 7/15/17 - 37.3C, 7/16 /17 - 37.3C, 7/17/17 - 37.3C, 7/18/17 - 37.4C, 7/19/17 - 37.4C, 7/20/17 - 37.4C, 7/21 /17 - 37.4C, 7/22/17 - 37.4C, 7/23/17 - 37.5C, 7/24/17 (Plasma Thawer 2 only) 37.5C, 7/25/17 - 37.4C, 7/26/17 - 37.4C, 7/27/17 - 37.3C, 7/28/17 - 37.4C, 7/29/17 - 37.4C, 7 /30/17 - 37.2C, and 7/31/17 - 37.4C. In January 2018, the Plasma Thawer temperature was documented as 37.1C on 1/8/18, 1/10/18, 1/22/18, 1/23/18, 1/24/18, and 1/27/18. The policy "Helmer Plasma Routine Operation and Maintenance" states "The temperature in the waterbath shall be at 36C +/- 1C when checked each day." The interview on 7/2/18 at 10:34am with the Blood Bank General Supervisor confirmed the temperatures were documented out of range. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the facility failed to ensure the stains used for the Gram Stain procedure were not expired prior to patient testing in September 2017. The findings include: The record review of the quality control documentation for September 2017 showed the Iodine lot #6836-00 expired on 9/1/17 and was used until the end of the month. During this time, seven patients had Gram Stains in which the expired Iodine was used. The interview on 7/3/18 at 10:00am with the Microbiology General Supervisor confirmed the expired Iodine was used for patient testing. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the facility failed to ensure the weekly and monthly maintenance required for the Helmer Plasma Thawer was performed for two of three months reviewed (July 2017 and January 2018). The findings include;<br>The record review of the "Plasma Thawer Quality Control" documentation showed no record of the weekly cleaning or monthly lubrication being performed in July 2017. The review of the January 2018 documentation showed the weekly cleaning was performed but the monthly required lubrication was not documented. The policy titled "Helmer Plasma Thawer Routine Operation and Maintenance Procedure" states "The thawer must be cleaned weekly and after a broken component has contaminated the bath." The policy lists the requirement for the lubrication of the basket assembly lift-out rail under the section titled "Monthly Maintenance". The interview on 7/2/18 at 10:34am with the Blood Bank General Supervisor confirmed the maintenance was not performed. |