

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0481909	<b>(X3) Date Survey Completed</b>  10/24/2023
<b>Name of Provider or Supplier</b>  Hunt Regional Pediatric Clinic Greenville	<b>Street Address, City, State</b>  5101 Wellington St Suite C, Greenville, 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>	An announced onsite initial survey was performed on October 24, 2023, and the laboratory was found to have standard level deficiencies. Pending an acceptable Plan of Correction (POC), recertification is recommended.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review laboratory's CMS (Centers for Medicare &amp; Medicaid Services) 209 form, American Proficiency Institute (API) testing records, and confirmed in interview, the laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform patient testing in the laboratory for 3 of 3 events in 2022 (Event 1,2 and 3) and 3 of 3 events in 2023 (Event 1,2 and 3). Findings included: 1. Review of the laboratory's CMS 209 form, submitted at time of survey, revealed 8 Testing Persons (TP) performing moderate complexity testing. 2. Review of the API testing records for 2022 and 2023 revealed the laboratory participated in the following events: 2022: Microbiology 1st, 2nd and 3rd Events Urine Cultures and Colony Counts TP-1,2,3,4,5,7 and 8 did NOT participate in 3 of 3 events in 2022. 2023: Microbiology 1st, 2nd and 3rd Events Urine Cultures and Colony Counts TP-1,2,3,4,5,7 and 8 did NOT participate in 3 of 3 events in 2023. Only TP-6 (also the Laboratory Director) participated in the above events in 2022 and 2023. 4. During an interview on 10/24/2023 at 11:32 a.m., in the facility breakroom, TP-1 confirmed the laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform patient testing in the laboratory for 3 of 3 events in 2022 (Event 1,2 and 3) and 3 of 3 events in 2023 (Event 1,2 and 3).</p>

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of policies and procedures, CMS-116 form, and confirmed in interview, the laboratory director failed to approve, sign and date 1 of 1 procedure used by testing personnel for performing hematology non waived patient testing in 2022. Findings Included: 1. During a tour of the facility on 10/24/2023 at 2:15 p.m., revealed the following hematology analyzer available for patient testing: ABX Micros 60 Hematology Analyzer (Serial Number: 901C598674) 2. Review of laboratory policy and procedure manual revealed the following hematology procedure used by testing personnel not signed and dated by the laboratory director: "ABX Micros 60 Procedure (Revision 5)" 3. Review of CMS-116, submitted at time of survey, revealed the laboratory performed 4,380 hematology tests annually. 4. During an interview on 10/24/2023 at 02:25 p.m., in the facility breakroom, TP-1 confirmed the laboratory director failed to approve, sign and date 1 of 1 procedure used by testing personnel for performing hematology non waived patient testing in 2022.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

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

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of Aidian Uricult Kit Intended Use Instructions, laboratory environmental records, urine culture log, and staff interview, the laboratory failed to ensure the room temperature range was within manufacturer's specifications for Aidian Uricult Kits prior to sample analyses for 3 of 3 months in 2023 (June-August). Findings Included: 1. During a tour of the facility on 10/24/2023 at 02:15 p.m., the surveyor observed the following boxes of Aidian Uricult Kits stored in the third laboratory drawer next to the refrigerator: Amount: 2 Boxes Lot Number: 1913761 Expiration Date: 11/19/2023 2. Review of the Aidian Uricult Kit Intended Use Instructions (Reviewed 01/2020) revealed the following: "Aidian Uricult Storage Store at 45 ...77 F (7 ...25 C) in the package provided. Protection from light and temperature fluctuations will ensure product stability to the expiration date." 3. Review of laboratory's environmental monitoring records for 3 of 3 months in 2023 (June-August) revealed the following laboratory room temperature range: 65 to 90 F The laboratory room temperature range was 13 degrees broader than the allowable temperature range for the storage of the Aidian Uricult kits. 4. Further review of the laboratory's environmental records revealed the laboratory temperature was outside of the allowable limit for the following 33 of 81 days reviewed in 2023 (June-August):

June 2023 a. Date: 06/17/2023 Temperature: 78 F Outside of allowable limit: 1 degree  
 b. Date: 06/19/2023 Temperature: 78 F Outside of allowable limit: 1 degree c. Date:  
 06/20/2023 Temperature: 78 F Outside of allowable limit: 1 degree d. Date: 06/21  
 /2023 Temperature: 78 F Outside of allowable limit: 1 degree e. Date: 06/26/2023  
 Temperature: 79 F Outside of allowable limit: 2 degrees f. Date: 06/28/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree g. Date: 06/30/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree h. Date: 06/31/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree July 2023 i. Date: 07/01/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree j. Date: 07/03/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree k. Date: 07/04/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree l. Date: 07/05/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree m. Date: 07/06/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree n. Date: 07/07/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree o. Date: 07/08/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree p. Date: 07/10/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree q. Date: 07/11/2023  
 Temperature: 79 F Outside of allowable limit: 2 degrees r. Date: 07/12/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree s. Date: 07/13/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree t. Date: 07/14/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree u. Date: 07/15/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree v. Date: 07/19/2023  
 Temperature: 79 F Outside of allowable limit: 2 degrees w. Date: 07/20/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree x. Date: 07/24/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree y. Date: 07/25/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree z. Date: 07/26/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree aa. Date: 07/29/2023  
 Temperature: 78 F Outside of allowable limit: 1 degree bb. Date: 07/31/2023  
 Temperature: 79 F Outside of allowable limit: 2 degrees August 2023 cc. Date: 08/01  
 /2023 Temperature: 78 F Outside of allowable limit: 1 degree dd. 08/03/2023  
 Temperature: 79 F Outside of allowable limit: 2 degrees ee. 08/04/2023 Temperature:  
 78 F Outside of allowable limit: 1 degree ff. 08/05/2023 Temperature: 78 F Outside of  
 allowable limit: 1 degree gg. 08/09/2023 Temperature: 78 F Outside of allowable  
 limit: 1 degree 5. Review of laboratory's, "Urine Culture Log", revealed the laboratory  
 performed 17 Uricult tests from June-August 2023. 6. During an interview on 10/24  
 /2023 at 02:25 p.m., in the facility breakroom, TP-1 confirmed the laboratory failed to  
 ensure the room temperature range was within manufacturer's specifications for  
 Aidian Uricult Kits prior to sample analyses for 3 of 3 months in 2023 (June-August).  
 Word Key: F- Fahrenheit C- Celcius

**D5803**

**TEST REPORT**  
 CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory urinalysis patient specimen logs, final patient reports and confirmed in interview, the laboratory failed to ensure 1 of 6 final urinalysis patient results reviewed was accurately transcribed in the patient's medical record in September 2023. Findings Included: 1. Review of laboratory urinalysis patient specimen logs revealed 24 patients having urinalysis testing in September 2023. Of the 24, 6 were reviewed for accuracy by the surveyor. 2. Review of final urinalysis

patient reports revealed the following patient result listed on the urinalysis log and NOT accurately transcribed in the patient's medical record: Date of Service: 09/20/2023 Sample Identification Number: 237009 Urinalysis Log Results: Leukocyte Negative Patient Medical Record Results: Leukocyte Trace 3. During an interview on 10/24/2023 at 02:25 p.m., in the facility breakroom, TP-1 confirmed the laboratory failed to ensure 1 of 6 final urinalysis patient results reviewed was accurately transcribed in the patient's medical record in September 2023.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of CMS-209 form, personnel records, and confirmed in interview, the technical consultant failed to perform annual personnel competency assessment for 5 of 8 testing persons (TP-1, 2, 3, 4, 5) who perform moderate complexity testing in 2022. Findings Included: 1. Review of CMS 209 form revealed moderate complexity bacteriology and urinalysis procedures were performed by TP-1 through TP-8. 2. Review of personnel records revealed annual competency assessments were NOT performed for TP-1, 2, 3, 4, and 5 in microbiology and urinalysis moderate complexity testing. (Note: The facility performed urine cultures/colony counts and urine sediment microscopic review.) 3. The facility office manager was asked to provide documentation of annual competency assessments for TP-1, 2, 3, 4, and 5 in moderate complexity microbiology and urinalysis testing for 2022 and none were provided. 4. During an interview on 10/24/2023 at 12:15 p.m., in the facility breakroom, the office manager confirmed the technical consultant failed to perform annual personnel competency assessment for 5 of 8 testing persons (TP-1, 2, 3, 4, 5) who perform moderate complexity testing in 2022.