Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0320482	01/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Norton Children's Medical Group - Prospect	9217 Us Highway 42, Prospect, KY	

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
D0000	A recertification survey was conducted on 01/10/2023, and the facility was found to not be in substantial compliance with the laboratory requirements at 42 CFR Part 493. The condition at 42 CFR 493.1409, laboratories performing moderate complexity testing; technical consultant was not met and additional standard level deficiencies were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on interview and record review, it was determined the facility had no procedure in place to verify the accuracy of the Uricult test utilized for urine colony counts. The findings include: Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification", completed by the Laboratory Director and dated 01/04/2023, revealed the facility used the Uricult to perform urine cultures. Review of the facility's Uricult (a method used for the detection of various types of bacteria that commonly caused urinary tract infections) test performance for urine collection, signed by the Laboratory Director on 08/26/2021, revealed there was not a procedure for performing the required accuracy verification. Interview with Testing Personnel #1, on 01/10/2023 at 12:45 PM, revealed the required accuracy verification was not being performed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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--

	At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview and record review, it was determined the facility failed to run a negative and positive control for urine colony counts. The findings include: Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification", completed by the Laboratory Director and dated 01/04/2023, indicated the facility used the Uricult, a moderate complex procedure subject to the requirements for quality control, to perform urine cultures. Review of the facility's Uricult (a method used for the detection of various types of bacteria that commonly caused urinary tract infections) test performance for urine collection, signed by the Laboratory Director on 08/26/2021, revealed there was not a procedure for performing the required quality controls. Interview with Testing Personnel #1, on 01/10/2023 at 12:45 PM, revealed the required quality controls were not being performed.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on interview and record review, it was determined the facility did not currently have a qualified Technical Consultant (TC). This failure had the potential to impact the quality of laboratory testing, as there was no one performing the duties of a TC. The findings include: Review of email correspondence the surveyor received from the TC of record, on 12/20/2022, revealed the TC was closing their laboratory consulting business effective 01/01/2023. Review of the "Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA)" document, signed by the Laboratory Director (LD) and dated 01/04/2023, revealed no one held the position of TC. Review of the "CLIA Application for Certification", completed by the LD and dated 01/04 /2023, revealed the facility performed two (2) non-waived, moderate complex tests: the complete blood count (a set of medical laboratory tests that provide information about the cells in a person's blood) and the Uricult (a test used for the detection of various types of bacteria that commonly cause urinary tract infections). Review of the TC of record's personnel file revealed the TC retired, effective 01/01/2023. Interview with Testing Personnel #1 and the Practice Manager, on 01/10/2023 at 11:40 AM, revealed the facility did not have a TC and the LD was acting as the TC. Interview with the LD, on 01/10/2023 at 11:50 AM, revealed the facility did not have a TC. Further interview revealed several options were discussed to fill the void of the TC position, such as the LD or the nurse practitioner serving as the TC. However, even though he and the nurse practitioner had the education requirements, neither met the requirements for the clinical experience.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education

	and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on interview and record review, it was determined the facility did not have a qualified Technical Consultant (TC). This failure had the potential to impact the quality of laboratory testing as there was no one performing the duties of a TC. The findings include: Review of email correspondence the surveyor received from the TC of record, on 12/20/2022, revealed the TC was closing their laboratory consulting business effective 01/01/2023. Review of the "Laboratory Personnel Report (CLIA)" document, signed by the Laboratory Director (LD) and dated 01/04/2023, revealed no one held the position of TC. Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification", completed by the LD and dated 01/04/2023, revealed the facility performed two (2) non-waived, moderate complex tests: the complete blood count (a set of medical laboratory tests that provide information about the cells in a person's blood) and the Uricult (a test used for the detection of various types of bacteria that commonly cause urinary tract infections). Review of the TC of record's personnel file revealed the TC retired, effective 01/01 /2023. Interview with Testing Personnel #1 and the Practice Manager, on 01/10/2023 at 11:40 AM, revealed the facility did not have a TC and the LD was acting as the TC. Interview with the LD, on 01/10/2023 at 11:50 AM, revealed the facility did not have a TC. Further interview revealed several options were discussed to fill the void of the TC position, such as the LD or the nurse practitioner serving as the TC. However, even though he and the nurse practitioner had the education requirements, neither met the requirements for the clinical experience. The clinical experience must include hands-on experience performing clinical testing or a formal rotation through a medical residency program or laboratory internship program.