Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0677021	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Childrens Clinic	7672 Airways, Southaven, MS	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory specimen collection and labeling policies, and interview with staff at 2:00 pm on the day of survey, the laboratory failed to follow the laboratory's written policy and procedure for labeling of patient specimens. The laboratory's written labeling policy requires testing personnel to label microtubes with the patient name and date of birth. Findings include: One patient specimen for a CBC was observed with no label on it. According to the staff no information was being written or attached to the patient specimen after collection. The patient's date of birth was entered into the AcT Diff hematology analyzer prior to processing and the patient's name was written on the report after printing from analyzer. This does not comply with the lab's written labeling policy.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics

	of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records from last survey, 12/20/16 through day of survey, and interview with staff at 4:00 pm on 11/28/18, the laboratory failed to document the QC results for urine media (URICULT Urine Culture CLED/EMB paddle system.) Findings include: On the day of survey, review of the Urine Culture QC log indicated that the laboratory was using Escherichia coli (ATCC 25922) and Pseudomonas aeruginosa (ATCC 27853) as positive growth controls for each new batch or shipment of URICULT. On the following dates a new lot number of URICULT paddles was put into use with incomplete control results documented (sterility or colony counts). The laboratory performed approximately 285 Uricults during this time frame, January 2018 until November 2018. 1/26/18 - URICULT Uricheck lot number - 7H24A - no sterility results 4/25/18 - URICULT Uricheck lot number - 8A31A - no sterility results 8/27/18 - URICULT Uricheck lot number - 8D20A - no QC or sterility results
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality control (QC) records for urine cultures from last survey, 12/20/16 through day of survey and interview with staff on 11/28/18, the laboratory reported patient results when QC was not acceptable on the URICULT Urine Culture CLED/EMB paddle system. Findings include: Review of the urine QC culture log revealed 2 organisms were used as positive controls for the URICULT CLED/EMB paddle system for each new lot number or shipment. On 4/25/18 when Lot number 8A31A was tested, Pseudomonas aeruginosa was reported as 0 colonies when it should have been positive for growth. Lot number 8A31A of URICULT CLED/EMB was put into use when the QC was not valid and patient results were reported using this lot from 4/25/18 through 8/27/18.