

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0988472	(X3) Date Survey Completed 07/31/2019
Name of Provider or Supplier Doctors Clinical Laboratory	Street Address, City, State 1685 Winnetka Circle, Rolling Meadows, IL	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the technical supervisor (TS); the laboratory failed to follow written quality control procedures for the antimicrobial susceptibility tests performed. Findings include: 1. The laboratory's individual quality control plan (IQCP) and the Mueller Hinton Plates and Sensitivity Disks (MHSD) quality control (QC) logs from May through July of 2019 were reviewed. 2. The IQCP required testing personnel (TP) to perform weekly testing of pathogenic control organisms for drug sensitivity and/or resistance. The zone sizes to the various drug discs, their lot numbers and expiration date, and the media's lot number and expiration date must be recorded in the MHSD-QC log. 3. The MHSD-QC logs revealed the following: *The pathogenic organisms were tested only 1 week in the months of May, June, and July of 2019. *The TP failed to document the lot number and expiration dates of the media used for the susceptibility test in the months of June and July of 2019. 4. On a Recertification survey conducted on 07/31/2019 at 2:30 PM, the TS and TP confirmed the above findings.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report</p>

destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the technical supervisor (TS); the laboratory failed to accurately and reliably enter patient-specific data from their requisition into the patient's electronic medical records (EMR), for 1 (Patient-CX3) out of 8 patients. Findings include: 1. The patients' final reports from the EMR and their requisitions were reviewed. 2. The review revealed that 1 out of 8 patients' information was inaccurately enter into the EMR: Patient-CX3's requisition states patient's date of birth as 04/09/1939, the date of birth reported from the Patient-CX3 EMR is 04/19/1939. 3. On a Recertification survey conducted on 07/31/2019 at 2:00 PM, the TS confirmed the above findings.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the technical supervisor (TS); the laboratory failed to indicate information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability, for 1 (Patient-D9) out of 8 patients. Findings include: 1. The patients' final reports from the EMR and their requisitions were reviewed. 2. The review of 8 patients' final reports revealed the following: *Patient-D9's requisition included a request for Urine Culture testing and sensitivity. *Patient-D9's final report does not include results from a urine Culture test. 3. The laboratory failed to indicate in the test report the reason a urine culture test was not performed on Patient-D9. 4. On a Recertification survey conducted on 07/31/2019 at 2:00 PM, the TS confirmed the above findings.