

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0957636	(X3) Date Survey Completed 06/18/2024
Name of Provider or Supplier Uc Reproductive Medicine At Kettering	Street Address, City, State 3533 Southern Blvd, Suite 4100, Kettering, OH	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultant (CC), Technical Supervisor (TS) and the General Supervisor (GS) based on the responsibilities of the position and at a frequency determined by the laboratory. This deficient practice had the potential to affect 750 out of 750 patients tested under the specialty of Hematology from 02/01 /2024 to 06/18/2024. Findings Include: 1. Review of the laboratory's Form CMS-209 approved by the Laboratory Director on 06/10/2024, revealed one individual listed and qualified by the Laboratory Director to function as a CC and one individual to function as both TS and GS. 2. Review of the laboratory's "Competency Assessment" policy and procedure, not approved via signature and date by the Laboratory Director, found no mention of instructions for the CC, TS or GS competency assessment. 3. The Inspector requested an approved competency assessment policy and procedure for the CC, TS and GS, and competency assessment documentation for the CC, TS and GS based on the responsibilities of the position from the LD. The LD confirmed the laboratory did not have an approved competency assessment policy and procedure, did not perform a competency assessment for the CC, TS and GS and was unable to provide the requested information. The interview occurred on 06/18/2024 at 9:45 a.m.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p>

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 record review and an interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures for specimen rejection of semen samples collected for analysis. This deficient practice had the potential to affect 750 out of 750 patients tested under the specialty of Hematology from 02/01/2024 through 06/18/2024. Findings Include: 1. Review of the laboratory's "Specimen Rejection and Stat Notification" policy and procedure, not approved via signature and date by the Laboratory Director, found the following statement: "Semen Analysis: Rejected specimens will be documented in the Significant Event Log" 2. The inspector requested documentation of specimen rejection for semen samples, and approved policies and procedures for the rejection of semen samples collected for analysis from the LD. The LD confirmed there was no documentation of semen sample rejection and no approved policy or procedure for semen sample rejection collected for analysis. The interview occurred on 06/18/2024 at 10:55 a.m.

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 record review and an interview with the Laboratory Director (LD), the LD failed to ensure policies and procedures were approved, signed and dated before use. This deficient practice had the potential to affect 750 out of 750 patients tested under the specialty of Hematology from 02/01/2024 through 06/13/2024. Findings Include: 1. Review of the Form CMS-209 approved on 06/10/2024 by the new/current LD, listed the new/current LD since the previous inspection. 2. Review of the form CMS-116 stated the new/current LD had assumed the role on 02/01/2024. 3. Review of the laboratory's "UC Center for Reproductive Health at Kettering Laboratory Reproductive Policy and Procedure Manual" page provided on the date of inspection, revealed the new/current LD review signature and date of 06/14/2024. 4. On 06/18/2024 at 11:30 a.m., the new/current LD confirmed policies and procedures were not approved, via signature and date before use.