

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0997826	(X3) Date Survey Completed 08/22/2018
Name of Provider or Supplier S I R M - C I	Street Address, City, State 5401 N Knoxville Ave, Ste 102, Peoria, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #1 and the laboratory director (LD); the laboratory failed to test proficiency testing (PT) samples the same number of times as patient samples in 2 of 4 PT events in 2017. Findings Include: 1. Review of College of American Pathologists (CAP) PT records from 2017 found that 2 of 4 PT events for semen analysis (SEM) and sperm morphology and motility (SPCD) were performed by two TP prior to submission to CAP, as documented on the attestation statements . a. CAP SPCD-B 2017 - TP#1 and TP no longer at facility b. CAP SEM-B 2017 - TP#1 and TP no longer at facility 2. Review of the laboratory policy, "Proficiency Testing Policy ", found in the laboratory's policy and procedure manual, stated the following on page 1: "2. Analysis of proficiency testing materials should be performed in the same manner as regular patient specimens." 3. On survey date 8-22-2018, at 10:55 am, TP#1 confirmed that PT samples for SPCD-B 2017 and SEM-B 2017 were ran by both TP prior to submission of PT results to CAP. TP#1 confirmed semen analysis for patients samples are not typically performed by multiple testing personnel prior to reporting patient test results. 4. On survey date 8-22-2018, at 1:15 pm, the LD confirmed the above findings.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory records and interviews with testing personnel (TP) #1 and the laboratory director (LD); the laboratory failed to retain proficiency testing (PT) documentation for 8 of 8 College of American Pathologists (CAP) PT events in 2016 through 2018. Findings Include: 1. Surveyor requested at 10:15 am, on 8-22-2018, PT records for semen analysis testing for the past two years. 2. Review of CAP semen analysis (SEM) and sperm morphology and motility (SPCD) PT records found the laboratory failed to retain the following documentation: a. SEM-B 2016 - No attestation statement and no testing records. b. SEM-A 2017 - No testing records. c. SEM-B 2017 - No testing records. d. SEM-A 2018 - No testing records. e. SPCD-B 2016 - No attestation statement and no testing records. f. SPCD-A 2017 - No attestation statement and no testing records. g. SPCD-B 2017 - No testing records. h. SPCD-A 2018 - No testing records. 3. Review of the laboratory policy, "Proficiency Testing Policy", stated on page 2, "10. PT records must be maintained for a minimum of two years." 4. On survey date 8-22-2018, at 1:15 pm, the above findings were confirmed by TP#1 and the LD.

D5473

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records and interviews with testing personnel (TP) #1 and the laboratory director (LD); the laboratory failed to test staining material for intended reactivity each day of use for hematology testing for 5 of 5 patient test dates reviewed. Findings Include: 1. Review of patient test results for semen analysis found for 5 of 5 patient test dates reviewed STAT III Andrology Stain reactivity was not performed or documented. Patient Identification Test Date P1 08-01-2018 P2 06-15-2018 P3 07-03-2018 P4 04-20-2018 P5 05-30-2018 2. Interview with TP #1 and the LD, on 8-22-2018, at 1:15 pm, confirmed that the quality of STAT III Andrology Stain failed to be documented each day of semen analysis testing. 3. On 8-22-2018, at 1:00 pm, TP#1 confirmed 44 semen analysis patients were tested between 5-16-2018 to 8-22-2018.