

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0712106	(X3) Date Survey Completed 02/04/2020
Name of Provider or Supplier Hshsmg Urology - Effingham	Street Address, City, State 414 W Virginia Ave, Effingham, 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
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299 for routine chemistry testing. Findings Include: 1. The laboratory failed to perform control procedures using the number and frequency specified by the laboratory's individual quality control plan (IQCP) for prostate specific antigen (PSA) testing for 2 of 6 patient testing dates reviewed and for 4 of 10 calibration dates reviewed. See D5445 A and B. 2. The laboratory failed to ensure two levels of quality control (QC) materials were acceptable prior to reporting patient test results for prostate specific antigen (PSA) testing on the Qualigen Fastpack IP system for 1 of 6 patient test dates reviewed. See D5481.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

A. Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to perform control procedures using the number and frequency specified by the laboratory's individual quality control plan (IQCP) for prostate specific antigen (PSA) testing for 2 of 6 patient testing dates reviewed. Findings include: 1. Review of the IQCP for total PSA testing on the Qualigen Fastpack IP system indicated external quality control (QC) testing will be done "with each new lot#/shipment/calibration and weekly". 2. Review of patient tests results found that for 2 of 6 patient test dates reviewed the laboratory failed to perform the weekly quality controls as indicated in the IQCP. Patient Identification Test Date P1 01-10-2020 P3 06-17-2019 3. Review of the Qualigen Fastpack IP system total PSA quality control log found for the first patient test date (01-10-2020) weekly QC was performed on 12-23-2019 and then not performed again till 01-15-2020. No weekly QC was documented for the week of 12-30-2019 and 01-06-2020. 4. Review of patient testing logs identified an additional 89 patients who had results reported for total PSA during the weeks of 12-30-2019 and 01-06-2020 (12-30-2019 to 01-14-2020) when no weekly QC was performed/documented. 5. Review of the Qualigen Fastpack IP system total PSA quality control log found for the second patient test date (06-17-2019) weekly QC was performed on 06-05-2019 and then not performed again till 06-19-2019. No weekly QC was documented for the week of 06-12-2019. 6. Review of patient testing logs identified an additional 41 patients who had results reported for total PSA during the week of 06-12-2019 (06-12-2019 to 06-18-2019) when no weekly QC was performed/documented. 7. On survey date 02-04-2020, at 3:25 pm, TP#2 confirmed the laboratory failed to perform weekly quality controls as indicated in the laboratory's IQCP for PSA testing on the Qualigen Fastpack IP system for the time periods documented above. B. Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to perform control procedures using the number and frequency specified by the laboratory's individual quality control plan (IQCP) for prostate specific antigen (PSA) testing for 4 of 10 dates reviewed when calibrations were performed for prostate specific antigen (PSA) testing on the Qualigen Fastpack IP system. Findings include: 1. Review of the IQCP for total PSA testing on the Qualigen Fastpack IP system indicated external quality control (QC) testing will be done "with each new lot#/shipment/calibration and weekly". 2. Review of Qualigen Fastpack IP PSA calibration and quality control records found for 4 of 10 calibrations reviewed the laboratory failed to perform external quality controls as instructed in the laboratory's IQCP. Calibration Dates with no corresponding QC 01-16-2020 12-16-2019 08-19-2019 07-18-2019 3. Review of the Qualigen Fastpack IP system quality control log for PSA testing and the PSA patient test log identified 7 dates when QC was not performed following a calibration and PSA test results were reported for 70 patients. Testing Dates and PSA Patient Test Results Reported 07-18-2019 - 5 Patients tested 08-19-2019 - 16 Patients tested 08-20-2019 - 19 Patients tested 12-16-2019 - 8 Patients tested 12-17-2019 - 11 Patients tested 01-16-2020 - 4 Patients tested 01-17-2020 - 7 Patients tested 4. On survey date 02-04-2020, at 3:25 pm, TP#2 confirmed the laboratory failed to perform external QC after calibrations for PSA testing on the Qualigen Fastpack IP system for 4 of 10 dates identified above as outlined in the IQCP.

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 laboratory records and interview with testing personnel (TP) #2; the laboratory failed to ensure two levels of quality control (QC) materials were acceptable prior to reporting patient test results for prostate specific antigen (PSA) testing on the Qualigen Fastpack IP system for 1 of 6 patient testing dates reviewed.

Findings Include: 1. Review of quality control records for PSA testing on the

Qualigen Fastpack IP system found for 1 of 6 patient testing dates reviewed the

weekly external level 1 quality control was outside the manufacturer's acceptable

range. Date Control Range Result 10-18-2019 0.67-1.6 ng/ml 0.29 ng/ml 2. Review of

the quality control log and corrective action documentation found the laboratory failed

to identify level 1 control was unacceptable. 3. Review of patient test records for 10-

18-2019 to 10-22-2019 found 24 patient test results were reported for PSA when the

weekly quality control results were unacceptable. 4. Interview with TP#2 on 02-04-

2020, at 3:25 pm, confirmed quality control results were outside the acceptable range

for PSA control testing on 10-18-2019 but the laboratory still reported 24 patient test

results for PSA.