

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2281694	(X3) Date Survey Completed 11/14/2024
Name of Provider or Supplier Wu Physicians In Il	Street Address, City, State 900 E Walnut St, Carbondale, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory test menu, laboratory policy and procedure manuals, proficiency testing records, and interviews with the technical consultant (TC) and Laboratory Director (LD), the laboratory failed to enroll in proficiency testing (PT) challenges in 2024 for one of one regulated endocrinology analyte, Human Chorionic Gonadotropin (HCG, 0555), affecting 42 patient results. Findings Include: 1. Review of the laboratory's test menu revealed the laboratory performed testing for the analyte HCG total serum quantitative in 2024 on a TOSOH Bioscience analyzer. 2. Interview with TC, on 11-14-2024, at 9:30 am, confirmed that the laboratory started testing patient samples in December 2023 for HCG. 3. Review of laboratory records found no PT was performed in 2024 for HCG. 4. Review of test volume records revealed from January of 2024 through November of 2024 that 42 HCG chemistry samples were analyzed in the subspecialty of endocrinology. 5. Interview with LD and TC, on 11-14-2024, at 9:30 am, confirmed that the laboratory failed to enroll in PT challenges in 2024 for HCG.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual, laboratory maintenance logs, and interview with Testing Personnel (TP)#1; the laboratory failed to retain maintenance logs for the Tosoh AIA - 360 analyzer for 2 of 11 months reviewed in 2024. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Checklist of Maintenance Checks and Calibrations" which stated to do the following: "Daily: Tosoh AIA - 360 per Maintenance Log Weekly and Bi-Weekly: Eyewash Tosoh AIA - 360 per Maintenance Log Monthly: Tosoh AIA - 360per Maintenance Log" 2. Review of laboratory Tosoh AIA - 360 maintenance log revealed the records lacked daily, weekly, and monthly maintenance for 2 of 11 months reviewed in 2024. 3. During the survey on 11-14-2024 at 11:01 am, TP #1 confirmed the Tosoh AIA - 360 maintenance logs for January 2024 and February 2024 were not retained by the laboratory.

D5200

GENERAL LABORATORY SYSTEMS

CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory test menu, laboratory test volume records, lack of documentation, and interview with the laboratory director (LD) and technical consultant (TC); the laboratory failed to perform bi-annual method accuracy evaluations for endocrinology testing in 2024 for four of four non-regulated analytes: Estradiol, Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), and Progesterone. (See D5217).

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory test menu, lack of documentation, laboratory test volume records and interview with the laboratory director (LD) and technical consultant (TC); the laboratory failed to perform bi-annual method accuracy evaluations for endocrinology testing in 2024 for four of four non-regulated analytes: Estradiol, Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), and

Progesterone, affecting 418 patient results. Findings include: 1. Review of laboratory's test menu revealed the laboratory performed testing for the analytes Estradiol, Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), and Progesterone in 2024. 2. Interview with TC, on 11-14-2024, at 9:30 am, confirmed that the laboratory started testing patient samples in December 2023 for estradiol, FSH, LH, and Progesterone. 3. Review of laboratory records revealed no documentation of bi-annual method accuracy evaluations or proficiency testing for the four non-regulated endocrinology analytes listed above in 2024 4. During the survey on 11-14-2024, at 9:30 am, the LD confirmed the laboratory failed to perform bi-annual method accuracy evaluations for 4 of 4 non-regulated analytes for 2024. 5. Review of test volume records revealed from January of 2024 through November of 2024 that the following samples were analyzed in the subspecialty of Endocrinology: A. 174 Estradiol B. 10 FSH C. 54 LH D. 180 Progesterone 6. Interview with LD and TC, on 11-14-2024, at 9:30 am, confirmed that the laboratory failed to perform bi-annual method accuracy evaluations for four of four non-regulated analytes in 2024.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual and interview with laboratory testing personnel (TP) #1; the laboratory failed to outline 1 of 14 required components of the Follicle Stimulating Hormone (FSH) test procedure for the specialty chemistry. Findings Include 1. Review of the laboratory's procedure manual identified the procedure for FSH testing titled "Checklist of Maintenance checks and Calibrations" failed to have the following required components of a test procedure: (5) Calibration and calibration verification procedures. 2. During survey date 11-14-2024 at 11:29 AM, TP # 1 confirmed the surveyor findings that the laboratory failed to have calibration verification procedures for FSH.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory policy and procedure manual, lack of documentation, laboratory calibration verification records, test volume records, and interview with laboratory testing personnel (TP) #1; the laboratory failed to conduct one of one calibration verification for the analyte Follicle Stimulating Hormone (FSH) every six months in 2024, affecting 10 patient results. Findings include: 1. Review of laboratory policy and procedure manual found the laboratory failed to have a procedure for FSH calibration verification (See D5403) 2. No calibration verification documentation for FSH was available to surveyors on the date of the survey 11/14/2024. 3. Review of test volume records revealed from January of 2024 through November of 2024 that a total of 10 FSH samples were analyzed by the laboratory since the start of patient testing. 4. During survey date 11-14-2024 at 11:28 AM, TP #1 confirmed the surveyor findings that the laboratory had failed to perform calibration verification for FSH in 2024.