

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0309288	(X3) Date Survey Completed 02/05/2026
Name of Provider or Supplier Paul G Smith Jr Do Plc	Street Address, City, State 2121 North Ocoee Street Suite 101, Cleveland, TN	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1).</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedures, laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, lack of records, and staff interviews, the laboratory failed to maintain accuracy of the microscopic urine sediment testing when the laboratory received 50% scores for three of four PT events in 2024 and 2025. The findings include: 1. Observation of the laboratory on 02/05/2026 at 9:00 a.m. revealed a microscope and patient logs used for microscopic analysis of urine sediment. During the observation, testing persons three and six stated that only the laboratory director performed urine microscopic patient testing. 2. A review of the laboratory's procedure titled "Microscopic Urinalysis" revealed "The Medical Director as the reviewing provider is verified by WSLH Proficiency Testing twice yearly. The results are documented in the UA Log and patient's chart by the nurse". 3. A review of the laboratory's WSLH PT records for Module 3320, Urine Sediment Identification, revealed the following analyte scores: 2024 Event 1: 50% 2024 Event 2: 50% 2025 Event 1: 50% 4. The laboratory was unable to provide documentation of additional studies for accuracy to the surveyor on the date of the survey (02/05/2026). 5. An interview with testing persons three and six on 02/05/2026 at 2:00 p.m. confirmed the survey findings.</p>
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient</p>

workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's procedures, laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure the urine sediment microscopic PT modules (three of four reviewed) were performed by personnel who routinely performed the patient testing in 2024 and 2025. The findings include: 1. Observation of the laboratory on 02/05/2026 at 9:00 a.m. revealed a microscope and patient logs used for microscopic analysis of urine sediment. During the observation, testing persons three and six stated that only the laboratory director performed urine microscopic patient testing. 2. A review of the laboratory's procedure titled "Microscopic Urinalysis" revealed "The Medical Director as the reviewing provider is verified by WSLH Proficiency Testing twice yearly. The results are documented in the UA Log and patient's chart by the nurse". 3. A review of the laboratory's WSLH PT attestation statements for Module 3320, Urine Sediment Identification, revealed two "analyst(s)" signatures that were not the laboratory director: 2024 Event 1 2024 Event 2 2025 Event 1 4. An interview with testing persons three and six on 02/05/2026 at 2:00 p.m. confirmed that the urine microscopic PT modules were completed by personnel who do not routinely perform patient testing in 2024 and 2025.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, a review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, lack of records, and staff interviews, the laboratory failed to document evaluation of analytes that were not graded by PT agency due to non-consensus for two of eight events reviewed for the complete blood count with differential (CBC w/Diff) and urine sediment microscopy testing in 2024 and 2025. The findings include: 1. Observation of the laboratory on 02/05/2026 at 9:00 a.m. revealed a Sysmex XN 530 (Serial #11423) used for CBC w/Diff, a microscope, and patient logs used for urine sediment microscopy patient testing. 2. A review of the laboratory's WSLH PT records revealed the following: Module 2290, Hematology- Comprehensive 2025 Event 1: Leukocytes (WBC) sample AF5-4 Result Status: "****" with a comment that stated " Non-consensus-Self-assessment Needed". Documentation of a Self-assessment was not available on the date of the survey (02/05/2026). Module 3320, Urine Sediment Identification 2025 Event 2: Sample SU-3 Result Status "****" with a comment that stated "Non-consensus-Self-assessment Needed". Documentation of a Self-assessment was not on the survey date (02/05/2026). 3. An interview with testing persons three and six on 02/05/2026 at 10:00 a.m. and 2:00 p.m. confirmed the survey findings.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's procedures, the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, and staff interviews, the laboratory failed to follow its Quality Assessment procedure for PT evaluation and corrective action for five of eight events reviewed for the complete blood count with differential (CBC w/Diff) and urine sediment testing in 2024 and 2025. The findings include: 1. Observation of the laboratory on 02/05/2026 at 9:00 a.m. revealed a Sysmex XN 530 (Serial #11423) used for CBC w/Diff, a microscope, and patient logs used for urine sediment microscopy patient testing. 2. A review of the laboratory's procedure titled "Quality Assurance Policy", in the "Proficiency Testing" section, revealed "We will evaluate the results of our proficiency testing with the lab director within one week of result report from WSLH. We will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency test result in effort to identify the cause of failure. If a cause is found, we will take necessary corrective action and re-evaluate PT results after the next PT challenge." 3. A review of the laboratory's WSLH PT records revealed the following: Module 2290, Hematology- Comprehensive 2024 Event 2: Performance Evaluation was not signed for review by the laboratory director. 2025 Event 3: Lymphocytes % sample AF5-11 Result Status: Fail. Documentation of corrective action was unavailable on the date of the survey (02/05/2026). The Performance Evaluation was not signed for review by the laboratory director. Module 3320, Urine Sediment Identification 2024 Event 1: Sample SU-2 Result Status: Fail. Documentation of corrective action was unavailable on the survey date (02/05/2026). The Performance Evaluation form was not signed for review by the laboratory director. 2024 Event 2: Sample SU-3 Result Status: Fail. Documentation of corrective action was unavailable on the survey date (02/05/2026). The Performance Evaluation form was not signed for review by the laboratory director. 2025 Event 1: Sample SU-2 Result Status: Fail. Documentation of corrective action was unavailable on the survey date (02/05/2026). 4. An interview on 02/05/2026 at 2:00 p.m. with testing persons three and six confirmed the survey findings.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's procedures, manufacturer operator manual, instrument reports, lack of records, final patient test review, and staff interviews, the laboratory failed to follow the manufacturer's instructions for the Sysmex XN 530 instrument used to perform complete blood count

with differential (CBC w/Diff) patient testing for 17 of 17 months reviewed in 2024, 2025, and 2026. The findings include: 1. Observation of the laboratory on 02/05/2026 at 9:00 a.m. revealed the Sysmex XN 530 (Serial #11423) used for CBC w/Diff patient testing. During the observation, testing persons three and six stated that the laboratory performed an instrument shutdown each Friday. 2. A review of the laboratory's policy titled "Quality Assurance Policy", in section "Quality Control and Instrumentation Program" revealed "Ensure manufacturer's directions followed in the operation of instrument as well as recommendations for maintenance". 3. A review of the Sysmex XN 530 operator's manual in Chapter 1, titled "Basic Operation," revealed the following: Section 1.1 titled "Overall flow of operation" provided a sequenced flow chart for the operation of the instrument that began with a startup, followed by a self-test through quality control and sample analysis, and ended with a shutdown when analysis had completed for the day or following 24 hours of continuous use. Section 1.2.3 titled "Executing a self-test" stated that when the instrument power is turned ON, the instrument automatically performed a self-test that includes a Background Check. Section 1.3 titled Shutdown stated "When you finish analysis work for the day, always perform shutdown. If analysis work will continue for more than 1 day, perform a shutdown once a day". 4. A review of the Sysmex report titled "Background Log" for 10/02/2024 through 02/05/2026 revealed that background checks were not performed as follows: 10/2024: 15 of 22 days 11/2024: 15 of 21 days 12/2024: 13 of 22 days 01/2025: 14 of 23 days 02/2025: 15 of 20 days 03/2025: 12 of 21 days 04/2025: 18 of 22 days 05/2025: 17 of 22 days 06/2025: 11 of 21 days 07/2025: 18 of 23 days 08/2025: 14 of 21 days 09/2025: 17 of 22 days 10/2025: 19 of 23 days 11/2025: 16 of 20 days 12/2025: 18 of 23 days 01/2026: 18 of 22 days 02/2026: 2 of 4 days 5. A review of final patient test reports revealed CBC w/Diff results were reported on the following dates without a documented background check: Patient M13040.3 reported on 02/27/2025 Patient 50283 reported on 08/29/2025 Patient M10200.0 reported on 01/13/2026 6. An interview with testing persons three and six on 02/05/2026 at 2:00 p.m. confirmed that the laboratory failed to perform an analyzer shutdown at the end of each workday or after 24 hours of continuous use, and to conduct a subsequent background check each day of patient testing in 2024, 2025, and 2026.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation of the laboratory, a review of the Laboratory Personnel Report (CLIA) (Form CMS-209), review of the laboratory's personnel records, lack of records, and staff interviews, the competency assessments for five of six testing personnel that performed complete blood count with differential (CBC w/Diff) patient testing on the Sysmex XN 530 instrument was performed by personnel that did not meet the qualification requirements of a technical consultant in 2024 and 2025. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, a review of the Form CMS-209, a review of the laboratory's personnel records, lack of records, and staff interviews, the competency assessments for five of six testing personnel that performed CBC w/Diff patient testing on the Sysmex XN 530 instrument was performed by personnel that did not meet the qualification requirements of a technical consultant in 2024 and 2025. The findings include: 1. Observation of the laboratory on 02/05/2026 at 9:00 a.m. revealed a Sysmex XN 530 (Serial #11423) used for CBC w/Diff patient testing. 2. A review of the Form CMS-209 completed for the survey revealed six testing personnel who performed CBC w/Diff patient testing, and the Laboratory Director was the Technical Consultant of record. 3. A review of the laboratory's personnel records revealed the following: Testing Person Two: Competency Assessment Dated 05/20/2025: Assessed By Testing Person Three. Testing Person Four: Competency

Assessments Dated 02/20/2024 and 06/10/2025: Assessed By Testing Person Three. Testing Person Five: Competency Assessment Dated 06/02/2025: Assessed By Testing Person Three. Testing Person Six: Competency Assessment Dated 07/31/2025: Assessed By Testing Person Three. Testing Person Seven: Competency Assessment Dated 01/20/2026: Assessed By Testing Person Three. 4. Education and experience documentation to qualify Testing Person Three as a technical consultant was unavailable on the date of the survey (02/05/2026). 5. An interview with testing persons three and six on 02/05/2026 at 10:00 a.m. and 2:00 p.m. confirmed the survey findings.