

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2297870	(X3) Date Survey Completed 07/29/2026
Name of Provider or Supplier Bloom Pediatrics	Street Address, City, State 28625 Northwestern Hwy Suite 100, Southfield, MI	
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
D0000	A recertification survey was performed on July 29, 2026 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1230 Condition: General laboratory systems. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient 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 record review and interview with the technical consultant, the laboratory failed to perform proficiency testing as it would perform patient testing for two (M2 2025 and FH16-A 2026) of five testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed the following events when proficiency testing was not tested by personnel who routinely perform testing or how it would routinely perform patient testing: a. The American Association of Bioanalysis Medical Laboratory Evaluation (AAB-MLE) proficiency testing event M2 2025 included a review of the event's "Proficiency Testing Survey Exception Form". The form included a section stating, "Upon documentation review, the PT samples for this event were run twice initially (one set reported, one set saved)." b. The College of American Pathologists' event FH16-A 2026 included an attestation showing the technical consultant was the testing personnel for this event. 2. An interview on 7/29/26 at 12:30 pm with the technical consultant confirmed patient

	testing is not routinely performed in duplicate. 3. A review of the laboratory's Form CMS-209, signed by the laboratory director on 7/28/26, did not show the technical consultant was designated as testing personnel. 4. A review of the technical consultant's personnel file revealed a lack of testing personnel training or testing personnel competency assessments. 5. An email received on 7/30/26 at 3:01 pm from the technical consultant confirmed they had not been routinely performing patient testing.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to ensure testing personnel and the laboratory director attested to the routine integration of its proficiency testing samples into the patient workload for four (Event M1 2025, Event M2 2025, Event M3 2025, and FH16-B 2026) of five testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed a lack of attestation statements for the following events: a. American Association of Bioanalysis Medical Laboratory Evaluation (AAB-MLE) Event M1 2025. b. AAB-MLE Event M2 2025. c. AAB-MLE Event M3 2025. d. College of American Pathologists' event FH16-B 2026. 2. An interview on 7/29/26 at 12:30 pm with the technical consultant confirmed the above findings.
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 record review and interviews, the laboratory failed to establish competency assessment policies to assess technical consultant competency (refer to D5209 A), failed to follow its competency assessment policies to perform testing personnel competency assessments (refer to D5209 B), and failed to document its evaluations of proficiency testing performance (refer to D5221).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

This STANDARD is not met as evidenced by:

. A. Based on record review and interview with the technical consultant, the laboratory failed to establish competency assessment policies to assess technical consultant competency for two (July 2024 to July 2026) of two years reviewed. Findings include: 1. A review of the laboratory's personnel records revealed a lack of documentation of technical consultant competency assessments performed between July 2024 and July 2026. 2. A review of the laboratory's "CBC Maintenance Procedure 2026", approved by the laboratory director without a date of implementation, included a section titled "Bi-annually" stating, "Complete competency checklist for each employee who runs lab tests using the Coulter DxH 500 Analyzer." This section of the maintenance policy did not address how the laboratory assesses competency of its technical consultants. 3. An interview on 7/29/26 at 12:12 pm with the technical consultant confirmed the laboratory had not established a competency assessment policy to include how it assesses technical consultant competency. B. Based on record review and interview with the technical consultant, the laboratory failed to follow its competency assessment policies to perform testing personnel competency assessments for 16 (testing personnel 3, 6, 10, 12, 14, 16, 17, 23, 34, 37, 40, 47, 48, 49, 53, and 55) of 33 testing personnel competency assessment records reviewed. Findings include: 1. A review of the laboratory's "CBC Maintenance Procedure 2026", approved by the laboratory director without a date of implementation, included a section titled "Bi-annually" stating, "Complete competency checklist for each employee who runs lab tests using the Coulter DxH 500 Analyzer." 2. A review of 33 testing personnel competency assessment records revealed the following 16 testing personnel did not have semiannual competency assessments performed: a. Testing personnel #3 was hired on 9/16/25 and completed their training on 1/23/26. No documentation of competency assessments performed were present. b. Testing personnel #6 was hired on 5/6/25 and completed their training on 8/13/25. No documentation of competency assessments performed were present. c. Testing personnel #10 was hired on 6/17/25 and completed their training on 8/5/25. No documentation of competency assessments performed were present. d. Testing personnel #12 was hired on 9/15/25 and completed their training on 1/13/26. No documentation of competency assessments performed were present. e. Testing personnel #14 was hired on 6/17/25 and completed their training on 8/5/25. No documentation of competency assessments performed were present. f. Testing personnel #16 was hired on 5/6/25 with training completed on 7/17/25. No documentation of competency assessments performed were present. g. Testing personnel #17 was hired on 10/7/24 with training completed on 11/11/24. One competency assessment was present and completed on 7/23/25. h. Testing personnel #23 was hired on 6/14/24 with training completed on 6/14/24 and 7/23/25. The only competency assessment present was dated 8/1/24. i. Testing personnel #34 was hired on 10/16/25 with a training completion date of 11/20/25. No documentation of competency assessments performed were present. j. Testing personnel #37 was hired on 6/17/25 with a training completion date of 8/20/25. No documentation of competency assessments performed were present. k. Testing personnel #40 was hired on 1/21/25 with a training completion date of 2/21/25. No documentation of competency assessments performed were present. l. Testing personnel #47 was hired on 6/18/24 with a training completion date of 7/23/24. The only competency assessment present was dated 12/20/24. m. Testing personnel #48 was hired on 5/6/25 with a training completion date of 7/11/25. No documentation of competency assessments performed were present. n. Testing personnel #49 was hired on 6/17/25 with a training completion date of 8/5/25. No documentation of competency assessments performed were present. o. Testing personnel #53 was hired on 5/6/25

	with a training completion date of 8/6/25. No documentation of competency assessments performed were present. p. Testing personnel #55 was hired on 5/6/25 with a training completion date of 7/24/25. No documentation of competency assessments performed were present. 3. An interview on 7/29/26 at 11:33 am with the technical consultant confirmed competency assessments for the above testing personnel were not performed in accordance with the laboratory's policy.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to document its evaluations of proficiency testing performance for three (event M2 2025, event FH16-A 2026, and event FH16-A 2026) of five proficiency testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed the following events with unacceptable, outside of the grading range or included an incorrect response: a. The American Association of Bioanalysis Medical Laboratory Evaluation (AAB-MLE) event M2 2025 had the following results outside of the grading range or included an incorrect response: i. Basophil percentage differential sample nine. ii. Monocyte percentage differential sample nine. iii. Hematocrit sample nine. iv. Hemoglobin sample nine. A review of the laboratory's "Proficiency Testing Survey Exception Form" used by the laboratory to evaluate the testing event failed to include how it evaluated the incorrect results obtained for basophil percentage differential sample nine. b. The College of American Pathologists' (CAP) proficiency testing event FH16-A 2026 had the following specimens with unacceptable results: i. Red Blood Cell Count sample three. ii. Hematocrit sample three. The documentation did not include an evaluation of the unacceptable results obtained. c. The CAP proficiency testing event FH16-B 2026 had the following specimens with unacceptable results: i. Hematocrit sample FH16-07. ii. Platelet count sample FH16-08. The documentation did not include an evaluation of the unacceptable results obtained. 2. An interview on 7/29/26 at 12:30 pm with the technical consultant confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory director failed to ensure proficiency testing was performed as the laboratory would perform patient testing (refer to D6016 A), failed to ensure the proficiency testing specimens were integrated into the patient workload (refer to D6016 B), failed to document its evaluations of proficiency testing performance when the laboratory obtained unacceptable results (refer to D6019), and failed to ensure testing personnel performing moderate complexity testing met educational qualification requirements (refer to D6029).

D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the technical consultant, the laboratory director failed to ensure proficiency testing was performed as the laboratory would perform patient testing. Refer to D2007. B. Based on record review and interview with the technical consultant, the laboratory director failed to ensure the proficiency testing specimens were integrated into the patient workload. Refer to D2009.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory director failed to document its evaluations of proficiency testing performance when the laboratory obtained unacceptable results. Refer to D5221.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: . Based on record review and lack of documentation, the laboratory director failed to ensure testing personnel performing moderate complexity testing met educational qualification requirements. Refer to D6065.
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 record review and interview with the technical consultant, the technical consultant failed to follow its competency assessment policies to perform semiannual competency assessments (refer to D6053) and failed to perform testing personnel

	competency assessments at least annually after the first year the individual tested patients (refer to D6054).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the technical consultant failed to follow its competency assessment policies to perform semiannual competency assessments. Refer to D5209 B.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the technical consultant failed to perform testing personnel competency assessments at least annually after the first year the individual tested patients for seven (testing personnel 16, 17, 23, 40, 47, 48, and 55) of 33 testing personnel records reviewed. Findings include: 1. A review of the laboratory's "CBC Maintenance Procedure 2026", approved by the laboratory director without a date of implementation, included a section titled "Bi-annually" stating, "Complete competency checklist for each employee who runs lab tests using the Coulter DxH 500 Analyzer." The laboratory's policy requires testing personnel competency assessments to be performed semiannually. 2. A review of 33 testing personnel competency assessment records revealed the following seven testing personnel did not have competency assessments performed at least annually: a. Testing personnel #16 was hired on 5/6/25 with training completed on 7/17/25. No documentation of competency assessments performed were present. b. Testing personnel #17 was hired on 10/7/24 with training completed on 11/11/24. One competency assessment was present and completed on 7/23/25. c. Testing personnel #23 was hired on 6/14/24 with training completed on 6/14/24 and 7/23/25. The only competency assessment present was dated 8/1/24. d. Testing personnel #40 was hired on 1/21/25 with a training completion date of 2/21/25. No documentation of competency assessments performed were present. e. Testing personnel #47 was hired on 6/18/24 with a training completion date of 7/23/24. The only competency assessment present was dated 12/20/24. f. Testing personnel #48 was hired on 5/6/25 with a training completion date of 7/11/25. No documentation of competency assessments performed were present. g. Testing personnel #55 was hired on 5/6/25 with a training completion date of 7/24/25. No documentation of competency assessments performed were present. 3. An interview on 7/29/26 at 10:55 am with the technical consultant confirmed competency assessments for the above testing personnel were not performed at least annually.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

. Based on record review and lack of documentation, the laboratory failed to ensure testing personnel performing moderate complexity testing met educational qualification requirements. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and lack of documentation, the laboratory failed to ensure testing personnel performing moderate complexity testing met educational qualification requirements for one (testing personnel #17) of 56 testing personnel listed of Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed testing personnel #17 was hired on 10/7/24 and had documentation of a foreign degree with an English translation. No foreign equivalency was provided. 2. The surveyor requested documentation of foreign equivalency on 7/29/26 at 10:33 am and it was not provided. 3. The laboratory was given an additional seven days to provide the documentation, and it was not received.