

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0293247	(X3) Date Survey Completed 01/26/2026
Name of Provider or Supplier Bond & Steele Clinic Pa D/B/A Bond Clinic Pa	Street Address, City, State 199 Ave B Nw, Winter Haven, FL	
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	An announced CLIA recertification survey was conducted at AdventHealth Bond Clinic on 1/20/2026 to 1/26/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the lab failed to achieve satisfactory performance for the analyte urine microalbumin for testing event (TE) 1 of two TEs (1 & 2) reviewed for 2025. Findings included: 1. The laboratory participated in proficiency with the American Proficiency Institute. The proficiency testing for urine micro was reviewed. There were two test events in 2025. The Performance Summary for the 2nd Chemistry - Miscellaneous TE, with a date of 11/12/2025 was reviewed. The score was 0% (unsatisfactory analyte performance). 2. The General Supervisor confirmed the above during an interview on 01/20/2026 at 1:50 p.m.</p>
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the</p>

proficiency testing event.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the lab failed to take appropriate remedial action for the unsatisfactory analyte performance for the analyte urine microalbumin for 1 of 1 test event (TE 1 of 2025) that required remedial action. Findings included: 1. See D2087. 2. The Performance Review and Corrective Action Form, signed by the Laboratory Director on 12/11/2025 was reviewed. The laboratory identified the units reported mg/L (milligrams per liter) were different than what was supposed to be reported, which was mg/dL (milligrams for deciliter). There was no remedial action such as the retraining of staff documented. 3. The General Supervisor was interviewed on 01/20/2026 at 1:50 p.m. They confirmed the above data. 4. Interview with the Laboratory Director via electronic communication on 01/26/2026 confirmed they were aware of the requirement that remedial action for unsatisfactory analyte performance include staff education and documentation.

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 record review and staff interview, the laboratory failed to verify the accuracy of analytes not evaluated or scored by the proficiency testing program used by the laboratory, American Proficiency Institute (API), from the test event (TE) 1 of 2025 through TE3 of 2025 for the specialties or subspecialties of Bacteriology, Hematology, General Immunology, Routine Chemistry and Urinalysis. Findings included: 1. The API Proficiency Testing Performance Evaluation (PTPE) reports stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. The following API scores were documented as "Not Graded"; a) TE 2 Microbiology, for Culture Zone Diameter for Tetracycline (sample UR-06), Tobramycin (UR-06), and Sulfamethoxazole (UR-06) b) TE 3 Chemistry Core, for Total Bilirubin (samples CH-12 & CH-15), measured Low Density Lipoprotein Cholesterol (samples CH-11 & CH13) c) TE 2 Chemistry Core, for Total Bilirubin (sample CH-07), Folate (samples IA--07 & IA-09) d) TE 1 Hematology/Coagulation, for Urine Microscopy for Bacteria, Casts, Crystals, Epithelial Cells, Red Blood Cells & White Blood Cells (sample UMS-01), for Body Fluid Crystals (sample CYS-02), and for manual Blood Cell Identification for Basophil (Dif %), Eosinophil (Dif %), Lymphocyte (Dif %), Monocyte (Dif %), Neutrophil band (Dif %), Neutrophil segmented (Dif %), NRBC/100 WBC (Nucleated Red Blood Cells per 100 White Blood Cells) (Dif %), Platelet estimate (DIF), RBC Morphology (DIF) e) TE 1 Chemistry Core, for CK-MB (Creatine Kinase Muscle-Brain isoenzyme) (samples CM-01 through CM-05). 3. API PTPE reports were reviewed. a) TE 2 Microbiology was signed by the Laboratory Director (LD) on

07/30/2025. b) TE 3 Chemistry Core was signed by the LD on 10/08/2025. c) TE 2 Chemistry Core was signed by the LD on 06/26/2025. d) TE 1 Hematology /Coagulation Core was signed by the LD on 05/15/2025. e) TE 1 Chemistry Core was signed by the LD on 03/05/2025. The signed forms did not address any ungraded analytes. 4. An interview with the General Supervisor at 1:50 p.m. on 01/20/2026 confirmed the above. 5. Interview with the Laboratory Director via electronic communication on 01/26/2026 confirmed they were aware of the requirement to evaluate and document ungraded analytes.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on record review and interview, there failed to be a written procedures manual for all Hematology testing performed by the laboratory available for two of two years (2024-2026). Findings included: 1. Complete Blood Count (CBC) Quality Control (QC) records for 9/2024 indicated reruns of QC with N/A (not applicable) for QC performed for Level 1 on 9/10/2024, 9/16/2024, 9/17/2024, 9/18/2024, 9/20/2024 (three times), and 9/27/2024. There was no documentation for why the N/A was documented and if any corrective actions had been taken. No written procedure was provided for documentation of Hematology QC being rerun and what N/A on QC records indicated. 2. The Technical Consultant/Technical Supervisor on 1/21/2026 at 1:40 p.m. confirmed there was no written procedure for no documentation for why the N/A was documented, what N/A indicated, and if any corrective actions had been taken. 3. The procedure for ACL Elite Pro used for coagulation testing approved by the Laboratory Director on 1/27/2025 failed to include a written procedure for performing changes of reagent and QC lots for coagulation testing. 4. The Technical Consultant/Technical Supervisor on 1/21/2026 at 1:55 p.m. confirmed there was no written procedure for performing changes of reagent and QC lots for coagulation testing. 5. The Laboratory Director via email confirmed on 1/26/2026 at 5:35 p.m. he was aware of the requirement to have a written procedure manual for all phases of testing.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on patient reports and interview, two of two reports failed to accurately document the name and address of the laboratory location where the test was performed. Findings included: 1. Two patient final reports of what the practitioners and patients would be provided were reviewed. Patient Report #1 (PR#1) tested 11/1/2024 and Patient Report #2 (PR#2) tested on 1/22/2026 documented on the final report from the electronic medical record (EMR) an abbreviated laboratory name and a different address than the testing laboratory. 2. The Technical Consultant/Technical Supervisor on 1/22/2026 at 10:50 a.m. confirmed PT #1 and PT#2's final reports were what practitioners and patients would be provided and did not include accurate name and address of the laboratory location where the test was performed. 3. The Laboratory Director via email confirmed on 1/26/2026 at 5:35 p.m. he was aware of the requirement to have patient reports with the name and address of the laboratory location where the test was performed.

D6080

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to establish a policy to be onsite once every six months and failed to document any onsite visits from 1/1/2025 to 1/26/2026. Findings included: 1. The Laboratory Policy and Procedure failed to contain a policy to be onsite once every six months and to document any onsite visits. The Laboratory Director's job description provided on 1/22/2026 and the Quality Management Plan (QMP) approved by the Laboratory Director on 1/2/2025 and 1/5/2026, which was the laboratory's Quality Assurance plan, failed to include a policy to be onsite once every six months and failed to document any onsite visits from 1/1/2025 to 1/26/2026. 2. The Technical Consultant/Technical Supervisor on 1/22/2026 at 12:20 p.m. confirmed the laboratory failed to have an established policy for the Laboratory Director to be onsite once every six months and failed to have documentation of any onsite visits from 1/1/2025 to 1/22/2026. 3. The Laboratory Director via email confirmed on 1/26/2026 at 5:35 p.m. he was aware of the requirement to have an established policy to be onsite once every six months and to document any onsite visits and that this had not been performed.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure that the quality assessment program was established and maintained to ensure the quality

of laboratory services provided and to identify failures in quality as they occurred for two of two years (2024-2025). Findings included: 1. The Quality Management Plan (QMP) approved by the Laboratory Director on 1/2/2025 and 1/5/2026, indicated under Responsibilities- the Medical Director (Laboratory Director) was responsible for medical and technical policies, processes, and procedures, including those that pertain to personnel and test performance. No documentation was presented of the Laboratory Director of this laboratory reviewing QMP reports or identifying and correcting the listed deficient practices found during the recertification survey. a. The lab failed to achieve satisfactory performance for the analyte urine microalbumin for testing event (TE) 1 of two TEs (1 & 2) reviewed for 2025. (See D2807) b. The lab failed to take appropriate remedial action for the unsatisfactory analyte performance for the analyte urine microalbumin for 1 of 1 test event (TE 1 of 2025) that required remedial action. (See D2094) c. The laboratory failed to verify the accuracy of analytes not evaluated or scored by the proficiency testing program used by the laboratory, American Proficiency Institute (API), from the test event (TE) 1 of 2025 through TE3 of 2025 for the specialties or subspecialties of Bacteriology, Hematology, General Immunology, Routine Chemistry and Urinalysis. (See D5215) d. There failed to be a written procedures manual for all Hematology testing performed by the laboratory available for two of two years (2024-2026). (See D5401) e. Two of two reports failed to accurately document the name and address of the laboratory location where the test was performed. (See D5805) f. The Laboratory Director failed to establish a policy to be onsite once every six months and failed to document any onsite visits from 1/1/2025 to 1/26/2026. (See D6080) g. The Laboratory Director failed to ensure that prior to testing patients' specimens, all testing personnel received the appropriate training for all testing operations for one of one new Testing Personnel (TP-B) who performed High Complexity Testing. (See D6102) h. The Laboratory Director failed to ensure that the policy for monitoring Testing Personnel demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for one (TP-E) of five Testing Personnel (TP-A, B, C, D and H) who performed High Complexity testing for two of two years (2024-2025). (See D6103) 2. The Technical Consultant/Technical Supervisor on 1/22/2026 at 12:00 p.m. confirmed there was no documentation of the laboratory following its QMP plan or identifying the non compliance identified during the recertification survey. 3. The Laboratory Director via email on 1/26/2026 at 5:35 p. m. verified the above listed non compliance identified during the recertification survey.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(12)

(e)(12) 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 interview, the Laboratory Director failed to ensure that prior to testing patients' specimens, all testing personnel received the appropriate training for all testing operations for one of one new Testing Personnel (TP-B) who performed High Complexity Testing. Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 1/202/26, listed 5 Testing Personnel (TP-A, B, C, D and H) who performed High Complexity testing.

Only TP-B was a new Testing Personnel since the last recertification survey dated 10/31/2023. 2. The laboratory policy titled LAB.POL 04.20 Laboratory Competency Assessment approved by the Laboratory Director 1/2/2025 and 1/5/2026 stated in C. New Associates new employees would be trained and a checklist was to be completed and part of the associates permanent record. 3. Personnel record for TP-B documented initial competency on 11/13/2024 and date of hire provided by the Technical Consultant/Technical Supervisor on 1/20/2026 at 1:00 p.m. was 11/4/2024. There was no documentation of training between 11/4/2024 and 11/13/2024 of training for TP-B for the testing performed. 4. The Technical Consultant/Technical Supervisor on 1/20/2026 at 1:00 p.m. confirmed TP-B's personnel record did not include documentation of training between 11/4/2024 and 11/13/2024 of training for TP-B for the testing performed. 5. The Laboratory Director via email confirmed on 1/26/2026 at 5:35 p.m. he was aware of the requirement to have training documentation prior to testing patients' samples.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure that the policy for monitoring Testing Personnel demonstrated that they could perform all testing operations reliably to provide and report accurate results at this laboratory for one (TP-E) of five Testing Personnel (TP-A, B, C, D and H) who performed High Complexity testing for two of two years (2024-2025). Findings included: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 1/20/2026, listed 5 Testing Personnel (TP-A, B, C, D and H) who performed High Complexity testing. 2. The laboratory policy titled LAB.POL 04.20 Laboratory Competency Assessment approved by the Laboratory Director 1/2/2025 and 1/5/2026 stated competencies would be performed and documented annually. 3. Personnel record for TP-H, who was also the General Supervisor/Technical Consultant /Technical Supervisor failed to have documentation for Testing Personnel competencies for 2024 and 2025. The competency Assessment schedule for 2026 did not include a scheduled competency for TP-H. 4. The Technical Consultant/Technical Supervisor on 1/20/2026 at 12:30 p.m. confirmed there were no annual Testing Personnel competencies for TP-H performed and documented. 5. The Laboratory Director via email confirmed on 1/26/2026 at 5:35 p.m. he was aware of the requirement to have annual Testing Personnel competencies performed and documented.