Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2144466	05/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Holtville Family Practice, Llc	213 Lightwood Road, Suite 1, Deatsville, AL	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on reviews of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to implement a mechanism to verify the accuracy of the White Blood Count (WBC) Differential, a regulated analyte. The surveyor noted the PT failures occurred in two consecutive events out of three in 2025. The findings include: 1. A review of the API PT records revealed the WBC Differential evaluations were unsuccessful for the following events: a) 2025 Hematology Second Event, 60 percent b) 2025 Hematology Third Event, 48 percent 2. A review of the PT performance review and corrective action documentation revealed the following findings. A) 2025 Hematology

	Second Event reran PT specimens, but results were still outside acceptable limits, calibrated analyzer and verified Quality Controls. B) 2025 Hematology Third Event, Testing Personnel did not follow the API instructions to use the correct PT specimen source when analyzing the specimens. 3. TP1 confirmed the above findings during the exit conference on 05-04-2026 at 1:38 PM.
D2121	HEMATOLOGY CFR(s): 493.851(a) (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. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records and interview with Testing Personnel 1 (TP1), the laboratory received failing scores for the White Blood Cell (WBC) Differential, a regulated test. The surveyor noted the laboratory failed in two consecutive PT events out of three in 2025. The findings include: 1. A review of the API PT records revealed the laboratory received unsatisfactory scores for the 2025 Hematology 2nd and 3rd Events on the WBC Differential for the following PT events. A) 2025 Hematology-Neutrophils, 2nd event = 60 Percent; 3rd event = 40 percent B) 2025 Hematology-Lymphocytes, 2nd event = 20 percent; 3rd Event = 0 percent C) 2025 Hematology-Monocytes, 2nd event = 20 percent; 3rd Event = 0 percent 2. TP1 confirmed the above findings during the exit conference on 05-04-2026 at 1:38 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the temperature log sheets, the package inserts for Hematology DxH 500 Series Control, and an interview with the Testing Personnel 1 (TP1), the laboratory failed to document the corrective action when the refrigerator temperature was outside the manufacturer's specified range. The surveyor noted refrigerator temperature was out of range for 1 of the 12 days in November 2024 and 1 of the 16 days in September 2025 prior to patient testing. The findings include: 1. A review of the temperature log sheets revealed the refrigerator temperature was outside the manufacturer's acceptable range on November 18, 2024 and September 17, 2025. 2. A review of the package insert for the manufacturer's temperature requirement to store QC materials revealed, "Storage Temperature: The controls must be stored at 2 - 8 degrees Celsius (36-46 degrees Fahrenheit) when not in use". 3. TP1 confirmed the above findings during the exit conference on 05-04-2026 at 1:38 PM.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the 2024-2026 Beckman Coulter (BC) DxH 520 Hematology analyzer maintenance logs and an interview with the Testing Personnel 1 (TP1), the laboratory failed to document performance of the monthly maintenance, as per the manufacturer's instructions. The surveyor noted there was no documentation of monthly maintenance for 16 of the 22 months reviewed in 2024-2026. The findings include: 1. A review of the BC DxH 500 Hematology analyzer maintenance logs revealed the BC DxH 520 analyzer had no documentation of the monthly maintenance for the following months. a) June-December 2024 b) January-July 2025; November 2025 c) February 2026 2. A further review of the BC DxH 520 analyzer maintenance log form revealed a place to document the monthly maintenance, "Cleaning the WBC Bath Filter". 3.TP1 confirmed the above findings during the exit conference on 05-04-2026 at 1:38 PM.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on reviews of the 2024-2026 Hematology Quality Control (QC) records for the Beckman Coulter (BC) DxH 520 analyzer, the laboratory Policy and Procedure (P&P) manual and interview with the Testing Personnel 1 (TP1), the laboratory failed to ensure a written policy defining and guiding TP what process to follow when QC values were outside established limits after several runs. The surveyor noted one of the three QC levels was outside manufacturer's acceptable ranges on February 2025. The findings include: 1. A review of the BC DxH 520 QC records revealed Hematology QC Normal level was out of range for the Red Blood Cell Count and Hematocrit tests prior to analyzing eight patient samples on February 13, 2025. 2. A review of the P&P manual revealed no written policy and procedure for TP to follow when one or all QC levels have parameters with values outside manufacturer's acceptable ranges. 3. TP1 confirmed the above findings during the exit conference on 05-04-2026 at 1:38 PM.
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 a review of the Testing Personnel (TP) annual competency assessment records and an interview with the TP1, the Technical Consultant (TC) failed to assess and document the annual competency assessments for TP listed on the CMS-209 (Laboratory Personnel Report) performing moderate complexity testing. The surveyor noted two of the four TP had no documentation of the annual competency in 2025. The findings include: 1. A review of personnel evaluation records revealed the TC did not document the 2025 annual competency assessments for TP3 and TP4. 2. TP1 confirmed the above findings during the exit conference on 05-04-2026 at 1:38 PM.