Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441456	07/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Blessing Health Hannibal Main Laboratory	100 Medical Drive, Hannibal, MO	

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 validation survey was performed on July 23, 2026. The laboratory was found to be in compliance with condition-level CLIA requirements. The following Standard-level deficiencies were cited.
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: Based on review of the training and competency assessment of employees policy, review of testing personnel competency assessment records and interview with the laboratory manager, the laboratory failed to establish a competency assessment procedure that ensures 7 of 7 testing personnel (TP) were assessed for each specific test procedure performed for 2 years (July 2024 to July 2026). Findings: 1. The CLIA Laboratory Personnel Report (Form CMS 209) listed 7 employees as TP. 2. Review of the Training and competency assessment of employees policy revealed the policy failed to ensure TP were assessed for each specific test procedure performed. 3. Review of TP competency assessment records from 2025 revealed 7 TP were assessed for each testing specialty rather than each specific test procedure performed. 4. By interview on July 23, 2026, at 9:00 am, the laboratory manager confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection.

	(a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the Post-Vasectomy Semen Examination (Sperm Count) policy, a lack of documented temperature for specimens received, and an interview with the Laboratory Manager, the laboratory failed to check and document the temperature of semen specimens delivered to the laboratory for 2 of 2 years (July 2024 to July 2026). Findings: 1. The Post-Vasectomy Semen Examination (Sperm Count) policy, page 1, Specimen:, stated "specimen needs to be kept at an ambient temperature (20 degrees to 37 degrees Celsius)." 2. The laboratory could not provide documentation for temperatures recorded for semen specimens received by the laboratory. 3. From July 2024 to July 2026, the laboratory performed 29 sperm count examinations. 4. By interview on July 23, 3036, at 12:40 pm, the laboratory manager confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of laboratory policies and an interview with the laboratory manager, the laboratory failed to include quality control (QC) procedures in 2 of 4 microscopic examination procedures for two years (July 23, 2024, to July 23, 2026). Findings: 1. The Excel test list provided to the surveyor via email on June 29, 2026, listed the following microscopic examinations: a. Direct Wet Mount Preparations. b. KOH Preparations. c. Manual Microscopic Analysis of Urinary Sediment. d. Manual Semen Analyses (post vasectomy). e. Manual WBC Diff Procedures. f. Nasal Smears for Eosinophils. g. Pinworm Preparations. 2. A review of the sampling of the procedure revealed the following 2 out of 4 of the policies failed to include QC procedures for the following policies: a. Direct Wet Mount Preparations. b. KOH

	Preparations. 3. By interview on July 23, 2026, at 2:20 pm, the laboratory manager confirmed the above findings.
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: I. Based on observation of the laboratory, lack of temperature records, and an interview with the laboratory manager, the laboratory failed to monitor and document temperatures for 179 of 179 collection tubes stored by three blood draw stations for two years (July 23, 2024, to July 23, 2026). Findings: 1. Observations on July 23, 2026, at 2:45 pm, revealed that the following sampling of collection tubes were stored by 1 of the 3 draw stations outside the laboratory with the manufacturer's temperature requirement of 4 to 25 degrees Celsius: a. 55 tubes of BD Vacutainer SST (yellow top), Lot#6097429. b. 50 tubes of BD Vacutainer Lithium Heprin (Green top), Lot#5344985. c. 54 tubes (3 ml) of BD Vacutainer K2E (lavender top), Lot#6013745. d. 08 tubes of BD Vacutainer Sodium Citrate (Blue Top), Lot#6047457. e. 06 tubes (10 ml) of BD Vacutainer K2E (lavender top), Lot#526628. f. 06 tubes of BD Vacutainer Serum, Lot#5132902. 2. The laboratory was unable to provide documentation of monitored temperatures of the blood draw area. 3. In an interview on July 23, 2026, at 3:30 pm, the laboratory manager confirmed the above findings. II. Based on observations of the laboratory, review of the ultra-low freezer temperature records, and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's temperature requirements for 15 out of 15 boxes of calibration verification reagents stored in the freezer for 17 out of 17 months (March 2025 to July 2026). Findings: 1. Observation of the laboratory on July 23, 2026, at 2:50 pm revealed that an ultra-low freezer (Freezer #1) in the laboratory was in use, which stored 15 boxes of Validate calibration verification linearity test kits with the manufacturer's temperature requirement of -10 to -25 degrees Celsius. 2. The following sampling of 4 Validate calibration verification linearity test kits were observed stored in the ultra-low freezer: a. Vitamin D test set, Lot#10769186. b. LP test set (HDL-LDL), lot#10798927. c. GC4 (TBIL - DBIL). lot#10766322. d. Fertility test set (FSH, HCG, LH, prolactin, and testosterone), lot#10780894. 3. Review of the laboratory temperature records revealed that the laboratory switched to an ultra-low freezer on March 26, 2025, with the acceptable temperature range of -20 to - 40 degrees Celsius. 4. Review of the laboratory temperature records revealed that temperatures fell outside the required manufacturer's temperature range on the following number of days for 17 months (March 2025 to July 2026): 2025 a. March - 6 of 6 days. b. April - 29 of 29 days. c. May - 31 of 31 days. d. June - 30 of 30 days. e. July - 31 of 31 days. f. August - 31 of 31 days. g. September - 30 of 30 days. h. October - 31 of 31 days. i. November - 30 of 30 days. j. December - 31 of 31 days. 2026 a. January - 31 of 31 days. b. February - 28 of 28 days. c. March - 31 of 31 days. d. April - 30 of 30 days. e. May - 31 of 31 days. f. June - 30 of 30 days. e. July - 23 of

	23 days. 5. In an interview on July 23, 2026, at 3:30 pm, the laboratory manager confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory observations and interviews with the laboratory manager, the laboratory failed to ensure that 2 of 2 immersion oil tubes were labeled with identifying information, storage requirements, and expiration dates for two years (July 2024 to July 2026). Findings: 1. Observation of the laboratory on July 23, 2026, at 2:00 pm, revealed that 2 tubes of immersion on the bench top were not labeled with identifying information, storage requirements, and expiration dates. 2. By interview with the laboratory manager on July 23, 2026, at 2:10 pm, it was confirmed that the above tubes were not labeled with any information.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on laboratory observations and interviews with the laboratory manager, the laboratory failed to ensure that 1 of 1 bottles of immersion oil was not expired and available for use. Findings: 1. Observation of the laboratory on July 23, 2026, at 2:00 pm revealed 1 bottle of Epredia Resolve Oil Immersion high viscosity, lot number: 140733, expired March 36, 2026, and was available for use on the bench top. 2. By interview with the laboratory manager on July 23, 2026, at 2:10 pm, it was confirmed that the bottle of Oil Immersion had expired.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on laboratory observations, a review of manual differential quality control (QC) records, and an interview with the laboratory manager, the laboratory failed to document the positive and negative staining materials' intended reactivity each day of use for 2 of 2 years (July 2024 to July 2026). Findings: 1. Review of manual

	differential quality control records at 10:30 am revealed that the laboratory failed to document positive and negative staining materials for their intended reactivity for manual differential microscopic examinations. 2. Observation of the laboratory on July 23, 2026, at 2:00 pm revealed the laboratory used one Siemens Healthineer Hematek 3000 with a modified Wright stain pack to stain manual differentials. 3. From July 2024 to July 2026, the laboratory examined 4,136 manual differential slides. 4. An interview with the laboratory manager confirmed the above findings on July 23, 2026, at 3:30 pm.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. This STANDARD is not met as evidenced by: Based on a review of the Post-Vasectomy Semen Examination (Sperm Count) policy, a lack of documented quality control, and an interview with the Laboratory Manager, the laboratory failed to document the QC procedure for sperm count examinations examined on a hemocytometer for 2 of 2 years (July 2024 to July 2026). Findings: 1. The Post-Vasectomy Semen Examination (Sperm Count) policy, page 3, stated, " Perform controls the same as the patient, by following step 4 of the procedure listed above." Page 2, step 4 stated, Perform a scan of all major squares on the hemocytometer. Review the four large corners and the middle squares to determine if sperm are present, and then repeat for the second side as well (see below). This is important to verify the presence or absence of sperm in order to justify quantification." 2. The laboratory could not provide QC documentation for semen count examinations performed in duplicate in for 2 years (July 2024 to July 2026) on the hemocytometer. 3. From July 2024 to July 2026, the laboratory performed 29 sperm count examinations. 4. By interview on July 23, 3036 at 1:00 pm, the laboratory manager confirmed the above findings.