Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2324409	12/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Molecular Direct Llc	7444 W Wilson Ave - Suite 103, Harwood Heights, IL	

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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical supervisor (TS); the laboratory failed to ensure positive and negative quality control (QC) materials were tested each day of Gastrointestinal (GI) and Lower Respiratory (RPP) Polymerase Chain Reaction (PCR) Panel testing on the BioFire FilmArray Torch molecular system (Serial Number: TB04678) for four of four patients reviewed in the specialty of microbiology from the beginning on 09/01/2025 through the date of survey, 12/17/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "043 Quality Control Policy", which stated, under "E. Control Frequency", "2. Run appropriate controls with each run associated with testing." 2. Review of laboratory QC records for four of four patient testing dates reviewed found no documentation that positive and negative QC materials were tested on each day of GI and Lower RPP PCR Panel testing on the BioFire FilmArray Torch molecular system. Date: Patient: QC Performed: 10/08/2025 25-216-0000012 No 11/20/2025 25-316-0000001 No 12 /01/2025 25-258-0000026 No 12/08/2025 25-315-0000005 No 3. Interview with the TS on 12/17/2025, at 12:27 pm, confirmed the laboratory failed to ensure positive and negative QC materials were tested each day of GI and Lower RPP PCR Panel testing on the BioFire FilmArray Torch molecular system for four of four patients reviewed in the specialty of microbiology from the beginning on 09/01/2025 through the date of survey, 12/17/2025.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)

	(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, the CMS-209 (Laboratory Personnel Report) Form, laboratory records, lack of documentation, and interview with the technical supervisor (TS); the TS failed to document training and evaluate competency of two of two testing personnel (TP) performing high complexity Gastrointestinal (GI) and Lower Respiratory (RPP) Polymerase Chain Reaction (PCR) Panel testing and four of four TP performing moderate complexity Clostridium (C.) difficile testing in the specialty of microbiology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "031 Personnel Qualifications and Responsibilities", which stated, under "V. Technical Supervisor ... Responsibilities:" "(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; "(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurate and proficiently." 2. Review of the CMS-209 (Laboratory Personnel Report) Form revealed four TP, two performing moderate complexity C. difficile testing (TP #3 and #4) and two performing both the moderate complexity C. difficile testing and high complexity GI and Lower RPP PCR testing (TP #1 and #2) in the specialty of microbiology. TP: Testing Complexity Performed: #1 Moderate and High #2 Moderate and High #3 Moderate #4 Moderate 3. Review of laboratory personnel records found no documentation of training and/or competency for all four TP performing high and/or moderate complexity microbiology testing. 4. Interview with the TS on 12/17/2025, at 9:07 am, confirmed the TS failed to document training and evaluate competency of two of two TP performing high complexity GI and Lower RPP PCR Panel testing and four of four TP performing moderate complexity C. difficile testing in the specialty of microbiology.