Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	99D2307137	09/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Spotitearly	408 Kibbutz Hama'Apil, Not Available, FN	

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 real-time remote recertification survey was performed on 09/03/25 and 09/04/25. The following standard-level deficiencies were cited.
D5311	Based on direct observation, manufacturer's instructions, patient requisition forms, patient test reports, and laboratory staff interview, the laboratory failed to document specimen acceptability for eight of eight patients. Findings included: 1. During a real-time virtual laboratory tour on 09/03/25 at approximately 03:00 am (US CST), the technical supervisor verified the laboratory performed BRCA (Breast Cancer) Germline Basic Panel (BRCA1-185delAG, BRCA1-5382insC, BRCA2- 6174delT) from a buccal swab specimen using the DNAgenoTek ORAcollect Dx collection kit. 2. Review of the "DNAgenoTek ORACollect Dx Product handbook" section "Pre-collection" stated, "ORAcollect Dx Kits can tolerate temperature fluctuations between -20C and 50C (-4F and 122F) during transport. 3. Review of eight patient requisitions and final patient reports revealed the laboratory failed to document the specimen temperature upon receipt to ensure acceptability for the following: a.Patient #6481 - Specimen collected on 08/25/25, received into the laboratory on 08/25/25, and reported on 08/27/25 b.Patient #6492 - Specimen collected on 08/25/25, received into the laboratory on 08/25/25, and reported on 08/27/25 c. Patient #6510 - Specimen collected on 08/23/25, received into the laboratory on 08/25/25, and reported on 08/27 /25 d. Patient #6525 - Specimen collected on 08/24/25, received into the laboratory on 08/25/25, and reported on 08/27/25 e. Patient #6579 - Specimen collected on 08/24 /25, received into the laboratory on 08/25/25, and reported on 08/27/25 f. Patient #6582 - Specimen collected on 08/24/25, received into the laboratory on 08/25/25, and reported on 08/27/25 g. Patient #6656 - Specimen collected on 08/24/25, received into the laboratory on 08/25/25, and reported on 08/27/25 h. Patient #6640 - Specimen collected on 08/24/25, received into the laboratory on 08/25/25, and reported on 08/27 /25 4. Interview on 09/04/25 at 01:45 am (US CST) with the Clinical Consultant and the Regulatory and Quality Assurance Vice President, confirmed the findings above. Key US CST = United States Central Standard Time
D5413	I. Based on direct observtion, the laboratory's establishment studies, manufacturer's

	instructions, environmental records, and laboratory staff interviews, the laboratory failed to ensure the laboratory's acceptable freezer ranges met the manufacturer's requirement for eight of eight months. Findings included: 1. During a real-time virtual laboratory tour on 09/03/25 at approximately 03:00 am (US CST), the technical supervisor verified the laboratory performed BRCA (Breast Cancer) Germline Basic Panel (BRCA1-185delAG, BRCA1-5382insC, BRCA2- 6174delT) from a buccal swab specimen. 2. Review of the laboratory's "BRCA Germline Basic Panel Validation Report" (VAL-0002) section "8. Materials and Methods", included "8.2. PCR Reaction mix: (containing dNTPs, MgCl2, hot-start DNA polymerase, ROX reference dye, AccuVue blue qPCR dye and stabilizers/QuantaBio), AccuStart Genotyping ToughMix Low cROX (2x) /QuantaBio / Agentek" as part of the testing process. 3. Review of the manufacturer's QuantBio AccuStart Genotyping ToughMix, Low ROX instructions revealed a storage requirement of "-25C to -15C". 4. Review of the laboratory's "POINTER IoT Temp/Humid Device Log" from 01/09/25 through 08/31/25 revealed the laboratory's acceptable freezer range was -30C to -17C (lower limit freezer temperature set colder than the manufacturer's instructions). 5. Interview on 09/03/25 at 05:30 am (US CST) with the Clinical Consultant and the Regulatory and Quality Assurance Vice President, confirmed the findings above. Word Key: dNTP = Deoxyribonucleotide Triphosphate MgCl2 = Magnesium Chloride DNA = Deoxyribonucleic Acid ROX = 6-carboxyl-X-rhodamine qPCR = Quantitative Polymerase Chain Reaction US CST = United States Central Standard Time II. Based on the direct observation, laboratory's procedure, manufacturer's instructions, environmental records, and laboratory staff interviews, the laboratory failed to ensure the laboratory's humidity ranges met the manufacturer's requirement for eight of eight months. Findings included: 1. During a real-time virtual laboratory tour on 09/03/25 at approximately 03:00 am (US CST), the technical supervisor verified the following: a. The laboratory performed BRCA (Breast Cancer) Germline Basic Panel (BRCA1-185delAG, BRCA1-5382insC, BRCA2- 6174delT) from a buccal swab specimen. b. The laboratory used the Eppendorf Centrifuge 5425 in the testing process. 2. Review of the laboratory's procedure titled, "WI3003 Genomic DNA Extraction" section, "9.6 DNA extraction-Bind and Wash DNA:" stated the following for use of the Eppendorf Centrifuge 5425: a."9.6.2 Transfer the mixture (including any precipitant) from the pre-treatment steps into the spin column and centrifuge at ?6000 x g (8000 rpm) for 1 min." b. "9.6.4 Add 500?l EPDW1 (buffer 2) to the spin column. Centrifuge at ?6000 x g (8000 rpm) for 1 min. Place the spin column on a fresh 2ml collection tube (provided) and discard the used collection tube and flow-through." c."9.6.5 Add 500?l of EPDW2 (buffer 3) and centrifuge for 3 min at 20,000 x g (14,000 rpm). The extended time in this step ensures that all the EtOH from the sample is removed and in the flow through. 3. Review of the "Eppendorf Centrifuge 5425 Operating Instructions" section "11.2 Ambient conditions" stated, "Relative humidity 10% - 75%, non-condensing.". 4. Review of the laboratory's "POINTER IoT Temp/Humid Device Log" from 01/08/25 through 08/31/25 revealed the laboratory's humidity ranges were 30% to 80% (upper limit humidity set higher than the manufacturer's requirement). 5. Interview on 09/03/25 at 04:30 am (US CST) with the Clinical Consultant and the Regulatory and Quality Assurance Vice President, confirmed the findings above. Word Key: EPDW = Endogenous Precipitation and Wash (Wash Buffer) EtOH = Ethanol Rpm = Revolutions Per Minute Min = Minute US CST = United States Central Standard Time