

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2113281	(X3) Date Survey Completed 01/20/2021
Name of Provider or Supplier Beta Biosciences, Llc	Street Address, City, State 1420 Nw Vivion, Suite 113, Kansas City, 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	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form, direct observations, review of laboratory policies, and confirmed in interview, the laboratory failed to ensure a unidirectional workflow for the molecular testing (PGx) on the KingFisher Flex system to ensure contamination prevention of patient specimens, equipment, instruments, reagents, and supplies. Findings: 1. Review of the submitted CMS-209 form revealed 2 testing persons (TP-1 and TP-2) for the laboratory. 2. Observations on 01/20/2021 at 1:20 pm revealed testing person-2</p>

(TP-2) performing decontamination of the fume hood in preparation for DNA extraction of patient specimens on the Kingfisher Flex system. TP-2 used 10% bleach to wipe down the fume hood followed by 70% isopropanol. Then she decontaminated the pipets located in the fume hood. As she was performing the decontamination process TP-2 required more paper towels and retrieved more paper towels from the counter next to the fume hood. As she finished with the paper towels she threw them away in a trash can located behind her. Each time TP-2 came out of the fume hood for new paper towels and to throw trash away she failed to dispose of the contaminated gloves and re-glove with sterile gloves. TP-2 changed her gloves once during the fume hood decontaminating process. After completing the decontamination process, TP-2 gathered a sealed bag of well plates and scissors from counter next to the fume hood and placed them in the fume hood. Under the fume hood, she opened the bag with the scissors and took out one well plate. Next, TP-2 exited from the fume hood and went to the counter to collect a sharpie pen, the elution buffer and a box of pipet tips. She returned to the fume hood and labeled the well plate and added the elution buffer. Next, she used the scissors to cut parafilm located on the counter and covered the well plate. She disposed of the used pipet in the trash can. She then placed the well plate next to the KingFisher Flex system. TP-2 exited the fume hood again and obtained from the counter two plexiglass stands, a bottle of 80% ethanol. She placed these materials in the fume hood. She returned to the fume hood and labeled two well plates and pipetted the ethanol into the well plates. Next, she used the scissors to cut parafilm located on the counter and covered the well plates. She disposed of the used pipet in the trash can. Then she placed the well plates next to the KingFisher Flex system. TP-2 exited the fume hood once again and obtained from the counter a bottle of Wash I and placed it in the fume hood. She returned to the fume hood and labeled a well plate and pipetted the wash I solution into the well plate. Next, she used the scissors to cut parafilm located on the counter and covered the well plate. She disposed of the used pipet in the trash can. Then she placed the well plate next to the KingFisher Flex system. TP-2 exited the fume hood and went into the storage room located within the laboratory and brought back with her a rack of patient specimens which she placed in the fume hood. TP-2 failed to change her laboratory coat and gloves when she walked into the storage room. TP-2 obtained from the counter a bottle of enhancer solution and a bottle of proteinase k and placed them in the fume hood. TP-2 then changed her gloves. She returned to the fume hood and labeled a well plate and pipetted the enhancer solution, patient specimens, and proteinase k into the well plate. She disposed of the used pipet in the trash can. Then she placed the well plate next to the KingFisher Flex system. Lastly, she loaded the well plates onto the Kingfisher Flex system. The laboratory testing person's actions failed to minimize contamination of patient specimens, equipment, instruments, reagents, and supplies. 2. Review of laboratory records revealed the following patient specimens were extracted on 01/20/2021: Patient IDs: 2101200016, 2101200019, 2101200038, 2101200042 3. Review of the laboratory policies titled "Extraction of Genomic DNA From Whole Blood Using the MagMax DNA Multi-Sample Ultra 2.0 Kit" revealed no documentation of how the laboratory ensured a unidirectional workflow or how to avoid contamination for PGX testing on the KingFisher Flex system instrument. 4. During the exit interview on 01/20/2021 at 2:30 pm, the General Supervisor was asked if there was a policy for decontamination procedures and he stated no, and testing persons were to decontaminate using the 10% bleach and 70% isopropanol. The General Supervisor was asked if the laboratory performed wipe tests of area where amplification procedures are used in order to monitor and prevent contamination. He stated the laboratory did not perform wipe tests. This confirmed the above findings. Word Key: PGx: pharmacogenomics

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, College of American Pathologists Proficiency Testing (PT) records (2019 A and B Events and 2020 A Event) and in interview with staff, the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. Findings included: 1. Review of laboratory records revealed the laboratory performed Pharmacogenetics (PGX) on the ThermoFisher Scientific Applied BioSystems Quantstudio 12K analyzer. 2. Review of CAP PT records from 2019 and 2020 revealed the following 2020 PGX-A event specimens with Exception Code [26] and [30]: a. CYP2C19 Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] b. CYP2C19 Clinical Management Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] c. CYP2D6 Genotype Specimen: PGX-02; Your Grade: See Note [30] d. CYP2D6 Gene Duplication Specimen: PGX-02; Your Grade: See Note [30] e. CYP2D6 Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] f. CYP2D6 Clinical Management Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] g. CYP2C9 Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] h. VKORC1 Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] i. CYP2C9/VKORC1 Clinical Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] j. CYP3A4 Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] k. CYP3A5 Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] l. TPMT Interpretation Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] m. TPMT Clinical Management Specimen: PGX-01; Your Grade: See Note [26] Specimen: PGX-02; Your Grade: See Note [26] Specimen: PGX-03; Your Grade: See Note [26] 3. The CAP Pharmacogenetics PGX-A 2020 Participant Summary stated the following: "Actions Laboratories Should Take when a PT result is Not Graded; The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception code, review, and document the acceptability of the performance as outlines below and retain documentation for review for at least 2 years. The actions laboratories should take include, but are not limited to: Code: 26; Exception Reason Code Description: Educational challenge; Action Required: Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by

the laboratory director for self-evaluation. Response to CAP is not required. Code: 30; Exception Reason Code Description: Scientific committee decision; Action Required: Applies to a response that is not penalized based on scientific committee decision. Document that the laboratory has reviewed the proper statistics supplied in the participant summary." 4. During an interview on 01/19/2021 at 11:35 am in a facility office, the General Supervisor was asked to provide documentation of a review for acceptability and any corrective actions for those analytes with exception codes. He stated that the laboratory did not evaluate acceptability of those analytes. After a review of the proficiency testing records the General Supervisor confirmed the above findings. Word Key: CYP2C19= Cytochrome P450 2C19 CYP2D6= Cytochrome P450 2D6 CYP2C9= Cytochrome P450 2C9 VKORC1= Vitamin K epOxide Reductase Complex CYP3A4= Cytochrome P450 3A4 CYP3A5= Cytochrome P450 3A5 TPMT= Thiopurine methyltransferase

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and confirmed in staff interview, it was revealed that laboratory policies were not approved, signed, or dated by the laboratory director before use. Findings included: 1. Review of the laboratory policy titled "Extraction of Genomic DNA From Buccal Cells Using the MagMax DNA Multi-Sample Ultra 2.0 Kit" stated the following: "Original Date: 07/22/2019, Revision Date: N/A, Effective Date: 07/22/2019 ... Approved By: [Name], Signature: [signed], Title: General Supervisor, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Compliance, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Director, Date: 03/01/2020" The signature under the name of the laboratory director was NOT signed by the laboratory director but signed by the Laboratory Compliance person. The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "Quality Control Guidelines" stated the following: "Original Date: 07/10/2020, Revision Date: N/A, Effective Date: 07/10/2020 ... Approved By: [Name], Signature: [signed], Title: General Supervisor, Date: 07/10/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Compliance, Date: 07/10/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Director, Date: 07/10/2020" The signature under the name of the laboratory director was NOT signed by the laboratory director but signed by the General Supervisor. The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "Open Array SNP Genotyping Analysis of Human Genomic DNA Using the QuantStudio 12K Flex" stated the following: "Original Date: 07/22/2019, Revision Date: N/A, Effective Date: 07/22/2019 ... Approved By: [Name], Signature: [signed], Title: General Supervisor, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Compliance, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Director, Date: 03/01/2020" The signature under the name of the laboratory director was NOT signed by the laboratory director but signed by the Laboratory Compliance. The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "Copy Number Variation Analysis of Human Genomic DNA Using the QuantStudio 7 Flex" stated the following: "Original Date: 07/22/2019, Revision Date: N/A, Effective

Date: 07/22/2019 ... Approved By: [Name], Signature: [signed], Title: General Supervisor, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Compliance, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Director, Date: 03/01/2020" The signature under the name of the laboratory director was NOT signed by the laboratory director but signed by the Laboratory Compliance person. The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "Extraction of Genomic DNA From Whole Blood Using the MagMax DNA Multi-Sample Ultra 2.0 Kit" stated the following: "Original Date: 07/22/2019, Revision Date: N/A, Effective Date: 07/22/2019 ... Approved By: [Name], Signature: [signed], Title: General Supervisor, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Compliance, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Director, Date: 03/01/2020" The signature under the name of the laboratory director was NOT signed by the laboratory director but signed by the Laboratory Compliance person. The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "RNase P Quantification of Human Genomic DNA Using the QuantStudio 7 Flex" stated the following: "Original Date: 07/22/2019, Revision Date: N/A, Effective Date: 07/22/2019 ... Approved By: [Name], Signature: [signed], Title: General Supervisor, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Compliance, Date: 03/01/2020 Approved By: [Name], Signature: [signed], Title: Laboratory Director, Date: 03/01/2020" The signature under the name of the laboratory director was NOT signed by the laboratory director but signed by the Laboratory Compliance person. The laboratory policy was not approved, signed and dated by the laboratory director. 2. During an interview on 01/20/2021 at 11:15 am in a facility office, the General Supervisor confirmed the above findings.

D5453

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(iv)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies, Extraction/Quantitation QC logs, patient records, and confirmed in interview, the laboratory failed to utilize two control materials during the extraction phase every day of PGx (pharmacogenomics) patient testing on the KingFisher Flex system for 3 of 3 days in 2020 (random sampling 12 /2020). Findings: 1. Review of laboratory policy titled: "Quality Control Guidelines" revealed the following: "VI. QUALITY CONTRL KINGFISHER FLEX - HUMAN GENOMIC DNA ISOLATION (PGx) 1. Record all Quality Control runs for the KingFisher Flex on FORM PGX1002a - Extraction Quantitation QC Log. Negative Control 1. Each KingFisher Flex extraction run must contain a negative control. 2. When processing swabs, as per SOP PGX1000 - Extraction of Genomic DNA from Buccal Cells Using the MagMax DNA Multi-Sample Ultra 2.0 Kit, a sterile Copan 4N6FLOQ swab will be used as the negative extraction control (EXT CTRL) and processed through quantitation. 3. When processing whole blood, as per SOP PGX1001 - Extraction of Genomic DNA from Whole Blood Using the MagMax

DNA Multi-Sample Ultra 2.0 Kit, nuclease free water will be used as the negative extraction control (EXT CTRL) and processed through quantitation ... Positive Control 1. Does not contain a positive control." 2. Review of Extraction/Quantitation QC Logs from December 2020 (random sampling) revealed only a negative extraction control (EXT CTRL) was documented on the following dates when patients were tested: 12/07/2020 Patient IDs: 2011250012, 2011250182, 201150198, 2012030166 12/11/2020 Patient IDs: 2012070001, 2012070004, 2012070005, 2012080001, 2012080004 12/31/2020 Patient IDs: 2012180500, 2012180501, 2012190422, 2012210020, 2012230343 The laboratory failed to perform two control materials during the extraction phase, including one that was capable of detecting errors in the extraction process for the above dates. 3. During an interview on 01/20/2020 at 10:07 am, the general supervisor confirmed the above findings. He was unaware he needed to perform 2 extraction controls every day of patient testing. According to the CMS-116 signed by the laboratory director on 01/19/2021, the facility performed 105,600 PGx testing annually.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of CMS 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance for 1 of 2 Testing Persons responsible for high complexity testing at least semiannually during the first year that testing persons analyze patient specimens. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person 1 listed to perform high complexity testing. 2. Review of personnel records from 2019 and 2020 revealed the following: Testing Person #1 Training documentation: 09/06/2019 Evaluator: Signed by the laboratory director of the facility at that time. 6-Month Competency Assessment: 03/01/2020 Evaluator: Signed by the Compliance person who was NOT listed on the CMS-209 as the Technical Supervisor Annual Competency Assessment: 07/23/2020 Evaluator: Signed by the Compliance person who was NOT listed on the CMS-209 as the Technical Supervisor The TS failed to evaluate and document performance at least semiannually during the first year of patient testing. 3. In an interview on 01/20/202 at 01:35 pm in the breakroom, Testing Person 1 was asked to provide documentation of semiannual competency assessment performed by the Technical Supervisor. No documentation was provided. This confirmed the above findings.