Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2133061	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Wise Diagnostics Llc	1776 Woodstead Ct Suite 107, The Woodlands, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's instructions, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimen storage for the Gastrointestinal panel testing on the Biofire Filmarray. Findings were: 1. Observations on 3/14/19 at 0945 hours in the laboratory revealed the laboratory received 12 stool specimens packed in either a mailer box (provided by the laboratory) and/or a FedEx mailer. Each stool specimen was received in ParaPak C&S media at ambient temperature for the GI testing on the Biofire Filmarray. Sample ID IFD000004227 IFD000004228 IFD000004229 IFD000004230 IFD000004231 IFD000004232 IFD000004233 IFD000004234 IFD000004235 IFD000004236 IFD000004237 IFD000004238 2. An interview with testing person #1 on 3/14/19 at 0948 hours confirmed the laboratory received stool specimens in either the laboratory box or the FedEx mailer. He also verified that no temperature was noted of the

	specimen throughout transport or receipt. 3. Review of the package insert for the FilmArray Gastrointestinal Panel (CE-IVD) Instruction Booklet (RFIT-PRT-OH3-04, June 2017) revealed under sample requirement "transport and storage - specimens should be processsed and tested as soon as possible, though they may be stored at room temperature or under refrigeration for up to 4 days." 4. Review of the verification studies for the GI panel for the BioFire FilmArray revealed no documentation of the stability study to ensure the stool samples in the ParaPak C&S media were stored at room temperature. 5. An interview with the laboratory owner on 3/14/19 at 1510 hours in the conference room confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in pre-analytic systems. Refer to D5311
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, laboratory verification records, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5421, D5423
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of the laboratory verification studies and confirmed in interview,

the laboratory failed to verify the manufacturer's specifications for accuracy by identifying the presence and absence of each of the target organism and subtypes for the Respiratory (RP) and Gastrointestinal (GI) patient testing on the Biofire FilmArray. A. Respiratory Panel B. Gastroinstestinal Panel Findings were: A. Respiratory Panel 1. Review of the FilmArray Respiratory Panel (RP) Instruction Booklet (RFIT-PRT-0435-03, June 2017) revealed under intended use "The following [19] organisms and subtypes are identified using the FilmArray RP: adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype 2009 H1, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae." 2. Review of the laboratory verification studies revealed the laboratory performed RP verification studies for the each of following 10 Biofire FilmArray analyzer. 2FA6D8C2 2FA05596 2FA3070 2FA03268 2FA02333 2FA00765 2FA05724 2FA00028 2FA03272 FA3698 3. Further review of the laboratory verification studies revealed no documentation of the presence and absence of each of the 19 organisms of the RP panel for 8 of the 10 FilmArray analyzers used in the laboratory. a. Review of the verification studies for analyzer with serial number 2FA3070 revealed no documentation of the presence of 11 of 19 organisms and subtypes (Chlamydia pneumoniae, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, influenza A subtype H1, influenza A subtype H3, influenza A subtype 2009 H1, parainfluenza virus 1, parainfluenza virus 2, and parainfluenza virus 4). b. Review of the verification studies for analyzer with serial number 2FA03268 revealed no documentation of the presence of 11 of 19 organisms and subtypes (coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, influenza A subtype H1, influenza A subtype H3, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 4, Bordetella pertussis, and Mycoplasma pneumoniae). c. Review of the verification studies for analyzer with serial number 2FA02333 revealed no documentation of the presence of 11 of 19 organisms and subtypes (adenovirus, Bordetella pertussis, coronavirus HKU1, coronavirus OC43, human metapneumovirus, influenza A subtype H3, influenza A subtype 2009 H1, parainfluenza virus 1, parainfluenza virus 2, and parainfluenza virus 4, mycoplasma pnuemoniae). d. Review of the verification studies for analyzer with serial number 2FA00765 revealed no documentation of the presence of 4 of 19 organisms and subtypes (human metapneumovirus, influenza A subtype 2009 H1, parainfluenza virus 1, parainfluenza virus 4, and mycoplasma pnuemoniae). e. Review of the verification studies for analyzer with serial number 2FA05724 revealed no documentation of the presence of 9 of 19 organisms and subtypes (coronavirus NL63, coronavirus OC43, human metapneumovirus, influenza A subtype H3, influenza A subtype 2009 H1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, and respiratory synctial virus). f. Review of the verification studies for analyzer with serial number 2FA00028 revealed no documentation of the presence of 9 of 19 organisms and subtypes (adenovirus, bordetella pertussis, chlamydia pneumoniae, coronavirus 229E, coronavirus NL63, influenza A subtype H1, parainfluenza virus 1, parainfluenza virus 2, and parainfluenza virus 4). g. Review of the verification studies for analyzer with serial number 2FA03272 revealed no documentation of the presence of 11 of 19 organisms and subtypes (adenovirus, coronavirus 229E, coronavirus NL63, influenza A subtype H1, influenza A subtype 2009 H1, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella pertussis, and Chlamydia pneumoniae). h. Review of the verification studies for analyzer with serial number 2F3698 revealed no documentation of the presence of 10

of 19 organisms and subtypes (adenovirus, coronavirus 229E, coronavirus NL63, influenza A subtype H1, influenza A subtype 2009 H1, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 4, Bordetella pertussis, Chlamydia pneumoniae). 4. An interview with the laboratory owner on 3/14/19 at 1200 hours in the conference room confirmed the above findings. He was unaware the laboratory was required to perform a positive and negative sample for the verification studies. B. Gastrointestinal Panel 1. Review of the package insert for the FilmArray Gastrointestinal Panel (CE-IVD) Instruction Booklet (RFIT-PRT-OH3-04, June 2017) revealed under intended use "The [21] following organisms and subtypes are identified using the FilmArray GI Panel: Campylobacter spp. (C. jejuni, C. coli, and C. upsaliensis), Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella spp., Vibrio spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Shiga-like toxin-producing E. coli (STEC) stx1 /stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, and sapovirus (I, II, IV, and V). 2. Review of the laboratory verification studies revealed the laboratory performed GI verification studies for the each of following 10 Biofire FilmArray analyzer. 2FA6D8C2 2FA05596 2FA3070 2FA03268 2FA02333 2FA00765 2FA05724 2FA00028 2FA03272 FA3698 3. Further review of the laboratory verification studies revealed no documentation of the presence and absence of each of the 21 organisms of the GI panel for 8 of the 10 FilmArray analyzers used in the laboratory. a. Review of the verification studies for analyzer with serial number 2FA3070 revealed no documentation of the presence of 8 of 21 organisms and subtypes (Plesiomonas shigelloides, Vibrio spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, and sapovirus (I, II, IV, and V). b. Review of the verification studies for analyzer with serial number 2FA03268 revealed no documentation of the presence of 8 of 21 organisms and subtypes (Plesiomonas shigelloides, Vibrio spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, adenovirus F 40/41. c. Review of the verification studies for analyzer with serial number 2FA0233 revealed no documentation of the presence of 8 of 21 organisms and subtypes (Plesiomonas shigelloides, Vibrio spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, adenovirus F 40/41. d. Review of the verification studies for analyzer with serial number 2FA05724 revealed no documentation of the presence of 8 of 21 organisms and subtypes (Vibrio spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Enteroaggregative E. coli (EAEC), Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Cryptosporidium, Entamoeba histolytic, adenovirus F 40/41. e. Review of the verification studies for analyzer with serial number 2FA00028 revealed no documentation of the presence of 9 of 21 organisms and subtypes (Yersinia entercolitica, Enteropathogenic E. coli (EPEC), Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella /Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, and sapovirus (I, II, IV, and V). f. Review of the verification studies for analyzer with serial number 2FA03272 revealed no documentation of the presence of 9 of 21 organisms and subtypes (Salmonella spp., Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Cryptosporidium, Cyclospora cayetanensis, Giardia lamblia, adenovirus F 40/41, astrovirus, norovirus GI/GII. g.

Review of the verification studies for analyzer with serial number 2FA3698 revealed no documentation of the presence of 9 of 21 organisms and subtypes (Campylobacter spp. (C. jejuni, C. coli, and C. upsaliensis), Salmonella spp., Yersinia entercolitica, Enteroaggregative E. coli (EAEC), E. coli O157, Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, norovirus GI/GII. 4. An interview with the laboratory owner on 3/14/19 at 1200 hours in the conference room confirmed the above findings. He was unaware the laboratory was required to perform a positive and negative sample for the verification studies. The laboratory performed 60,000 Biofire tests annually. II. Based on review of the manufacturer instructions, laboratory verification studies, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimens used for the accuracy assessments for each BioFire FilmArray for both the RP and GI panel. A. Respiratory Panel B. Gastrointestinal Panel A. Respiratory Panel 1. Review of the package insert for the FilmArray Respiratory Panel (RP) Instruction Booklet (RFIT-PRT-0435-03, June 2017) revealed under Verification of Loaner and repaired instruments "Proficiency samples should not be pooled or diluted." 2. Review of the laboratory verification studies revealed the laboratory performed RP verification studies for the each of following 10 Biofire FilmArray analyzer. 2FA6D8C2 2FA05596 2FA3070 2FA03268 2FA02333 2FA00765 2FA05724 2FA00028 2FA03272 FA3698 3. Review of the above RP verification studies revealed documentation that 4 of 10 analyzers used pooled proficiency samples. a. Review of the RP verfication studies for the FilmArray with Serial Number 2FA3070 revealed the laboratory performed pooled proficiency samples (API sample 2,3,4) as one of the sample source. b. Review of the RP verfication studies for the FilmArray with Serial Number 2FA02333 revealed the laboratory performed pooled proficiency samples (API sample 2,3,4) as one of the sample source. c. Review of the RP verfication studies for the FilmArray with Serial Number 2FA00765 revealed the laboratory performed pooled proficiency samples (API sample 8, 9, 10) as one of the sample source. d. Review of the RP verfication studies for the FilmArray with Serial Number 2FA03268 revealed the laboratory performed pooled proficiency samples (API sample 2,3,4) as one of the sample source. 4. Review of the testing person #1 on 3/14/19 at 1440 hours in the conference room confirmed the above findings. B. Gastrointestinal Panel 1. Review of the package insert for the FilmArray Gastrointestinal Panel (CE-IVD) Instruction Booklet (RFIT-PRT-OH3-04, June 2017) revealed under Verification of Loaner and repaired instruments "Proficiency samples should not be pooled or diluted." 2. Review of the laboratory verification studies revealed the laboratory performed GI verification studies for the each of following 10 Biofire FilmArray analyzer. 2FA6D8C2 2FA05596 2FA3070 2FA03268 2FA02333 2FA00765 2FA05724 2FA00028 2FA03272 FA3698 3. Review of the above GI verification studies revealed documentation that 3 of 10 analyzers used pooled proficiency samples. a. Review of the GI verfication studies for the FilmArray with Serial Number 2FA3070 revealed the laboratory performed pooled proficiency samples (API sample 1, 3) as one of the sample source. b. Review of the GI verfication studies for the FilmArray with Serial Number 2FA02333 revealed the laboratory performed pooled proficiency samples (API sample 1,3) as one of the sample source. c. Review of the GI verfication studies for the FilmArray with Serial Number 2FA03268 revealed the laboratory performed pooled proficiency samples (API sample 1,3) as one of the sample source. 4. Review of the testing person #1 on 3/14/19 at 1440 hours in the conference room confirmed the above findings. The laboratory performed 60,000 Biofire tests annually. III. Based on review of the manufacturer's instructions, laboratory verification studies, and confirmed in interview, the laboratory failed to document verification studies using the Viral Transport Media (VTM) Protocol that evaluated FilmArray RP performance when organisms are in a VTM sample matrix. Findings were: 1. Review of the

	FilmArray Respiratory Panel (RP) Instruction Booklet (RFIT-PRT-0435-03, June 2017) revealed under intended use "The following [19] organisms and subtypes are identified using the FilmArray RP: adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype 2009 H1, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydia pneumoniae, and Mycoplasma pneumoniae." 2. Review of the laboratory policies revealed the laboratory accepted RP specimens in viral transport media. 3. Review of the laboratory verification studies revealed no documentation of the RP verification studies using the VTM for the each of following 10 Biofire FilmArray analyzer. 2FA6D8C2 2FA05596 2FA3070 2FA03268 2FA02333 2FA00765 2FA05724 2FA00028 2FA03272 FA3698 3. An interview with the laboratory owner on 3/14/19 at 1420 hours in the conference room confirmed the above findings. He was unaware the laboratory should perform the verification studies according to how the laboratory received the specimens. The laboratory performed 60,000 Biofire tests annually.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observations, review of the manufacturer's instructions, review of the laboratory verification studies, and confirmed in interview, the laboratory failed to document complete establishment studies for the modified FDA-approved testing for the FilmArray Gastrointestinal (GI) Panel for the Biofire FilmArray. Findings were: 1. Review of the package insert for the Para-Pak C&S (SN10850, 12/16) stool media revealed under Biological Principles "Para-Pak C&S and Para-Pak Enteric Plus are modifications of Cary-Blair, which utilizes an isotonic non-nutritive, buffered solution to insure survival of bacterial pathogens and prevent overgrowth by commensal organisms. A pH indicator is incorporated to indicate acidic conditions in the tube which are not optimal for recovery of the organisms in question." 2. Review of the package insert for the FilmArray Gastrointestinal Panel (CE-IVD) Instruction Booklet (RFIT-PRT-OH3-04, June 2017) revealed under sample requirement "stool specimen collection stool specimens should be collected in Cary Blair transport media according to manufacturer's instructions." Furthermore, the package insert states under limitations, "the performance of this test has only been validated with human stool collected in Cary-Blair transport medium, according to the media manufacturer's instructions. It has not been validated for use with other stool transport media, raw stool, rectal swabs, endoscopy stool aspirates, or vomitus." 3. Observations on 3/14/19 at 0945 hours in the laboratory revealed the laboratory received 12 stool specimens

	stored in Para-Pak C&S media for patient testing for the GI Panel for the Biofire FilmArray; thus, modifying the FDA approved GI testing for the Biofire FilmArray, making it high complexity. Sample ID IFD000004226 IFD000004227 IFD000004228 IFD000004229 IFD000004230 IFD000004231 IFD000004232 IFD000004233 IFD000004234 IFD000004235 IFD000004236 IFD000004237 IFD000004238 4. Review of the laboratory verification studies revealed no documentation of the sensitivity, specificity, carryover, interference studies, and any other applicable performance specifications. 5. An interview with the laboratory owner via phone on 3 /20/19 at 1550 hours confirmed the above findings. He was unaware the laboratory modified the FDA approved testing. He assumed that the Para-Pak C&S media was okay for use.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records, and confirmed in interview, the laboratory quality assessment policies and procedures failed to to monitor & evaluate the overall quality of the analytic systems. (refer to D5421, D5423)
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control records, quality assessment records and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. (Refer to D6013, D6021)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by:

	Based on a review of the manufacturer's instructions, laboratory's verification records and interview of facility personnel, the laboratory director failed to ensure verification studies were complete for Respiratory and Gastrointenstinal panel testing on the BioFire FilmArray before reporting patient test results. (Refer to D5421)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, laboratory's verification records and interview of facility personnel, the laboratory director failed to ensure verification studies were complete for Gastrointenstinal panel testing on the BioFire FilmArray before reporting patient test results. (Refer to D5423)