Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0656094	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cleveland Clinic Main Lab	9500 Euclid Avenue Desk L21, Cleveland, OH	

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
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 records, patient test records and testing personnel (TP) interview, the laboratory failed to meet the analytical system requirements by not checking fluorescent stains for positive and negative reactivity each time of use for Fluorescence In Situ Hybridization (FISH) testing for 3 of 3 patient reports and 3 of 3 laboratory procedure manuals reviewed. Findings include: 1. Failure to check fluorescent stains for positive and negative reactivity each time of use for Fluorescence In Situ Hybridization (FISH) testing. See D5475.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test reports and laboratory personnel

interview, the laboratory failed to check fluorescent stains for positive and negative reactivity each time of use for Fluorescence In Situ Hybridization Testing (FISH) testing for 3 of 3 patient reports reviewed and 3 of 3 laboratory procedure manuals reviewed. Findings include: Item #1 1. Review of laboratory procedure manual #103136.3319, titled, "Fixed Pellet Probe procedure," dated 4/12/2017, under Section I., states, "Fluorescence in situ hybridization (FISH) is a molecular diagnostic technique utilizing labeled DNA probes to detect or confirm gene or chromosome abnormalities. During FISH probing, the specimen DNA (metaphase chromosomes or interphase nuclei) is denatured and a fluorescently labeled probe of interest is added to the specimen." 2. Review of laboratory procedure manual #103136.3357, titled," FISH WWTRI CAMTA1 Paraffin," dated 9/15/2017, under section II.B, states, "A positive control, BRTB, and a negative control (normal) tonsil are to be run with every batch." 3. Review of patient test report S18-XXXXX shows that patient test results were reported for WWTR1/CAMTA1. 4. Surveyor requested positive and negative quality control records for checking fluorescent stain reactivity for patient test report #S18-XXXXX and was not provided with requested records. 5. Review of laboratory record dated 02/13/2018, states, "Starting Sunday we are not going to run QC slides with most of our tests." 6. TS6 stated " there is no control, only internal control, no external control." The conversation occurred on 08/14/2018 at 1:28 PM. Item #2 1. Review of laboratory procedure manual #103136.4930, titled, "FISH on Cell Blocks Procedure," dated 5/15/2018, under Background and Principle, states, "tests approved for VP2000 cell block processing FISH for ALK, ROS1, RET." Under "Specimen requirements," it states, "The Immunohistochemistry (IHC) lab will cut 4 uM sections of the block and apply them to silanized or positively charged slides, " and "Put specimen and control slides (if paraffin) to be tested in a metal slide rack and place the rack in the oven at 60 to 65 degrees Celsius for 30-60 minutes." It further states in the procedure manual under "Scoring Slide," "Do not score nuclei with no signal of only one color (without a fused and/or broken apart signal). Score only those nuclei with one or more fish signals of each color." 2. Review of laboratory procedure manual #103136.3626 , titled, "Fish Quality Control," dated 5/8/2018, under "Quantitative Quality Control Slides made from new cell line blocks or fixed cell pellets," states, "quantitative quality control slides are to be tested from new tissue cuts or cell lines." 3. Review of patient test report #P18-XXXX shows that patient test results were reported for ALK, RET and ROS1 rearrangement. 4. Surveyor requested positive and negative quality control records for checking fluorescent stain reactivity for patient test report #P18-XXXXX and was not provided with requested records. 5. Review of laboratory record dated 02/13/2018, states, "Starting Sunday we are not going to run QC slides with most of our tests." 6. TS6 stated " there is no control, only internal control." The conversation occurred on 08/14/2018 at 1:31 PM. Item # 3 1. Review of laboratory procedure manual #103136.3319, titled, " Fixed Pellet Probe procedure," dated 4/12/2017, under Section I., states, "Fluorescence in situ hybridization (FISH) is a molecular diagnostic technique utilizing labeled DNA probes to detect or confirm gene or chromosome abnormalities. During FISH probing, the specimen DNA (metaphase chromosomes or interphase nuclei) is denatured and a fluorescently labeled probe of interest is added to the specimen." The same procedure manual further states, in "Section III -Analytic Activities," under "Probe mixture," "Each mixture contains volumes for one slide. Based on the number of slides in each run, determine volumes of individual reagents. In a microcentrifuge, combine the following order per slide, 0.5 ul probe of LSI BCR/ABL DF, LSI MLL BA and LSI ETV6 LSI RUNX1 DF." 2. Review of patient test report #S18-XXXXXX shows that 200 nuclei were scored per probe set and lists the following Anomaly: BCR/ABL1 at 0%, MLL at 0% and ETV6/RUNX1 at 0%. 4. Surveyor requested positive and negative quality control records for checking fluorescent stain reactivity for patient

	test report #S18-XXXXX and was not provided with requested records. 5. Review of laboratory record dated 02/13/2018, states, "Starting Sunday we are not going to run QC slides with most of our tests." 6. TS6 stated "no control slides other than internal controls." The conversation occurred on 08/14/2018 at 1:20 PM.