Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2117825	04/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Interlab Corp	9000 Nw 15th St Unit 1a, Doral, FL	

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	CCR# 2018004322 A complaint survey was conducted on April 9, 2018.Interlab Corp was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation and the interview with the laboratory director, laboratory failed to provide adequate space, required storage, and ventilation system that would properly remove vapors, fumes and excessive heat for the Histopathology and Cytology subspecialty laboratory chemicals. Findings included: Observation on 4/9 /18 at 2:30 PM revealed that; (1) following chemicals, stains and reagents; A- Bouins Solution -Anapath, for tissue fixation (label; formaldehyde, methanol, glacial acetic acid) Lot# 2065 Expiration date: 3/14 B- Papanicolaou Stain solution OG-6, Lot# 1705427, Expiration date: 3/2/18 C- 10% Formalin Fixative (NBF) Lot# 1323809 Expiration date: 8/15. Gallon bottles- 2 D- Protocol Formalin Lot# 280479 Expiration date: 1/2018. E- Hydrochloric acid 1.0N 1L Lot# C380750 Expiration date: 2016/04 /30 F- Hydrochloric acid solution N/10 (Normal/10) Lot# 130336 Expiration date: 02 /2015 G- Light Green Counter Stain REF STLGCPT Lot# 16110178 Expiration date: 2018/01/01 H- Solution in the glass bottle; had a label as Acid 5% Alcohol, with no date of preparation, expiration date or lot number. I- Ammonium Hydroxide 28% Lot# 1732014 Received date 1/16/18 (Label on bottle stated; Store locked up in well ventilated Space, but it was stored in regular cabinet under the counter top) J- Richard -Allan Scientific Clarifier-1, (label stated extremely flammable, was stored in regular cabinet) K- Cytoseal 60 Lot# 263527 Expiration date 7/2015 L- Methyl Alcohol; 1 gallon Lot# 275029 Expiration date 12/2015 M- Protocol Formalin - 1:10 Dilution (Buffered) Lot# 280479 Expiration date 1/2018 Gallon bottles-3 N- Richard Allan

	Scientific clarifier 1 gallon Lot# 275257 Expiration date 10/2015 O- 10% Formalin Fixative Lot# 1800411 Expiration date 1/18/2020, 8 Bottles, P- Platinum Line Xylenes- Mercedes Medical Lot# 1710706 10/20/2019 Q- White vinegar were observed in the laboratory; a) on top of the flammable storage cabinet, not in the flammable cabinet, b) in the regular cabinets, c) cabinets under the sink, d) on the floor in the laboratory and in the supply area, e) in the boxes on the floor, in a supply area with other storage cabinets, file cabinets, regular office supplies, slide storage, other storage cabinets and other supplies on shelves,leaving no adequate room to reach out for the chemicals or other supplies, and with no ventilation. There was a strong chemical smell on the floor where the laboratory was located and the smell continued throughout the laboratory during the time of the complaint investigation. There were no records of MSDS for the laboratory chemicals, stains, and reagents for chemical hazard, storage and handling at the time of complaint investigation. There were no records of OSHA (occupational safety and health administration) regulations and training at the time of complaint investigation. (2) f) FUMEGARD - activated carbon fume removal filter- date installed; 9/9/16 on the sticker, not functional. g) SHANDON -- activated carbon fume removal filter- date installed; 9/9 /16 on the sticker, functional, was not turned on- 4/9/18. h) FUMEGARD-no sticker as when was installed, functional, was not turned on- 4/9/18 i) Surgipath XYL -X50B air filter, no sticker to show when was installed, functional, was turned on -4/9/18. Laboratory did not have any maintenance records for the histology section fume hood air filters from 9/9/16 to 4/9/18. (3) Flammable storage cabinet had hazardous chemicals, expired, not part of the laboratory, not labeled as not part of the laboratory. Interview with Histopathology and Cytology subspecialty laboratory director at about 4:45 PM, confirmed findings (1), (2) and (3).
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review and the interview with the laboratory director, Histopathology and Cytology subspecialty laboratory failed to establish, access and observe safety procedures to provide the safety and sanitary conditions to the personnel. Findings included: Observation on 4/9/18 at 2:30 PM revealed that; (1) following chemicals, stains and reagents; A- Bouins Solution -Anapath, for tissue fixation (label; formaldehyde, methanol, glacial acetic acid) Lot# 2065 Expiration date: 3/14 B- Papanicolaou Stain solution OG-6, Lot# 1705427, Expiration date: 3/2 /18 C- 10% Formalin Fixative (NBF) Lot# 1323809 Expiration date: 8/15. Gallon bottles- 2 D- Protocol Formalin Lot# 280479 Expiration date: 1/2018. E- Hydrochloric acid 1.0N 1L Lot# C380750 Expiration date: 2016/04/30 F- Hydrochloric acid solution N/10 (Normal/10) Lot# 130336 Expiration date: 02/2015 G- Light Green Counter Stain REF STLGCPT Lot# 16110178 Expiration date: 2018 /01/01 H- Solution in the glass bottle; had a label as Acid 5% Alcohol, with no date of preparation, expiration date or lot number. I- Ammonium Hydroxide 28% Lot# 1732014 Received date 1/16/18 (Label on bottle stated; Store locked up in well ventilated Space, but it was stored in regular cabinet under the counter top) J- Richard -Allan Scientific Clarifier-1, (label stated extremely flammable, was stored in regular cabinet) K- Cytoseal 60 Lot# 263527 Expiration date 7/2015 L- Methyl Alcohol; 1

	gallon Lot# 275029 Expiration date 12/2015 M- Protocol Formalin - 1:10 Dilution (Buffered) Lot# 280479 Expiration date 1/2018 Gallon bottles-3 N- Richard Allan Scientific clarifier 1 gallon Lot# 275257 Expiration date 10/2015 O- 10% Formalin Fixative Lot# 1800411 Expiration date 1/18/2020, 8 Bottles, P- Platinum Line Xylenes- Mercedes Medical Lot# 1710706 10/20/2019 Q- White vinegar were observed in the laboratory; a) on top of the flammable storage cabinet, not in the flammable cabinet, b) in the regular cabinets, c) cabinets under the sink, d) on the floor in the laboratory and in the supply area, e) in the boxes on the floor, in a supply area with other storage cabinets, file cabinets, regular office supplies, slide storage other storage cabinets and other supplies on shelves,leaving no adequate room to reach out for the chemicals or other supplies, and with no ventilation. There was a strong chemical smell on the floor where the laboratory was located and the smell continued throughout the laboratory during the time of the complaint investigation. There were no records of MSDS for the laboratory chemicals and reagents for chemical hazard, storage and handling at the time of complaint investigation. (2) f) FUMEGARD - activated carbon fume removal filter- date installed; 9/9/16 on the sticker, not functional. g) SHANDON -- activated carbon fume removal filter- date installed; 9/9/16 on the sticker, functional, was not turned on- 4/9/18. h) FUMEGARD-no sticker as when was installed, functional, was not turned on- 4/9/18 i) Surgipath XYL -X50B air filter, no sticker to show when was installed, functional, was turned on -4/9/18. Laboratory did not have any maintenance records for the histology section fume hood air filters from 9/9/16 to 4/9/18. (3) Flammable storage cabinet had hazardous chemicals, expired, not part of the laboratory, not labeled as not part of the laboratory. (4) No liquid soap in the liquid soap bottle for hand wash in the laboratory. (5) No safety goggles in the laboratory. Interview with Histopathology and Cytology subspecialty laboratory director at about 4:45 PM, confirmed findings (1), (2), (3), (4) and (5).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the test requisition form and the final report review, laboratory failed to document the correct collection date on the final report for hrHPV-DNA (high-risk Human Papilloma Virus- Deoxyribonucleic acid) test. Findings included: Requisition form and report for patient #2, case surveyor selected for review on 4/9/18, reviewed on 4/10/18 had date collected as 3/29/18 on the test requisition form and date collected as 3/30/18 on final test report for hrHPV-DNA (high-risk Human Papilloma Virus- Deoxyribonucleic acid) test As the cytology supervisor had to go for the day on 4/9/18, laboratory had provided the patient's test reports later via e-mail on 4/10/18, there was no interview with the supervisor.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review and interview, Histopathology and Cytology subspecialty laboratory failed to follow the policy and procedure for; I- Storage of chemicals. II- Monitor the turnaround time for daily pending list for laboratory tests. There was no corrective action and no quality assessment review of the actions taken. Findings included: Observation on 4/9/18 at 2:30 PM revealed that; (i) following chemicals, stains and reagents; A- Bouins Solution -Anapath, for tissue fixation (label; formaldehyde, methanol, glacial acetic acid) Lot# 2065 Expiration date: 3/14 B- Papanicolaou Stain solution OG-6, Lot# 1705427, Expiration date: 3/2/18 C- 10% Formalin Fixative (NBF) Lot# 1323809 Expiration date: 8/15. Gallon bottles- 2 D- Protocol Formalin Lot# 280479 Expiration date: 1/2018. E- Hydrochloric acid 1.0N 1L Lot# C380750 Expiration date: 2016/04/30 F- Hydrochloric acid solution N/10 (Normal/10) Lot# 130336 Expiration date: 02/2015 G- Light Green Counter Stain REF STLGCPT Lot# 16110178 Expiration date: 2018/01/01 H- Solution in the glass bottle; had a label as Acid 5% Alcohol, with no date of preparation, expiration date or lot number. I- Ammonium Hydroxide 28% Lot# 1732014 Received date 1/16/18 (Label on bottle stated; Store locked up in well ventilated Space, but it was stored in regular cabinet under the counter top) J- Richard -Allan Scientific Clarifier-1, label stated extremely (flammable, was stored in regular cabinet) K- Cytoseal 60 Lot# 263527 Expiration date 7/2015 L- Methyl Alcohol; 1 gallon Lot# 275029 Expiration date 12/2015 M- Protocol Formalin - 1:10 Dilution (Buffered) Lot# 280479 Expiration date 1/2018 Gallon bottles-3 N- Richard Allan Scientific clarifier 1 gallon Lot# 275257 Expiration date 10/2015 O- 10% Formalin Fixative Lot# 1800411 Expiration date 1/18/2020, 8 Bottles, P- Platinum Line Xylenes- Mercedes Medical Lot# 1710706 10/20/2019 Q- White vinegar were observed in the laboratory; a) on top of the flammable storage cabinet, not in the flammable cabinet, b) in the regular cabinets, c) cabinet under the sink, d) On the floor, e) In the boxes on the floor. There were no records of MSDS for the laboratory chemicals and reagents at the time of complaint investigation. (i) Test requisition order slip and final report review on 4/10 /18 for specimen # C18-351 showed specimen collection date as 2/20/18 and test report date as 3/5/18. Reviewed Policy and procedure on 4/10/18 for; - Chemical storage and monitoring, - Turnaround time for routine and non-routine cases for the laboratory. Interview with Histopathology and Cytology subspecialty laboratory director at about 4:45 PM, confirmed the above findings of the chemicals stains and reagents in Histopathology and Cytology subspecialty laboratory, not stored as per the policy and procedure. As the cytology supervisor had to go for the day on 4/9/18, laboratory had provided the patient's test reports later via e-mail on 4/10/18, there was no interview with the supervisor. Also,there was no corrective action and no quality assessment review of the actions taken.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation, record review and interview, Histopathology and Cytology subspecialty laboratory had expired reagents in use and were not labeled as expired. Findings included: Observation on April 9, 2018 at about 2:30 PM revealed that; A- Cytology test specimen (C18-589) was collected on 3/22/18, in Thin Prep PAP test collection bottle that had expiration date of 2018-02-02. B- Bouins Solution -Anapath, for tissue fixation (label; formaldehyde, methanol, glacial acetic acid) Lot# 2065 Expiration date: 3/14 C- 1- Papanicolaou Stain solution OG-6, Lot# 1705427, Expiration date: 3/2/18 2- 10% Formalin Fixative (NBF) Lot# 1323809 Expiration date: 8/15. Gallon bottles- 2 3- Protocol Formalin Lot# 280479 Expiration date: 1 /2018. 4- Hydrochloric acid 1.0N 1L Lot# C380750 Expiration date: 2016/04/30 5- Hydrochloric acid solution N/10 (Normal/10) Lot# 130336 Expiration date: 02/2015 6- Light Green Counter Stain REF STLGCPT Lot# 16110178 Expiration date: 2018 /01/01 7- Solution in the glass bottle; had a label as Acid 5% Alcohol, With no date of preparation, expiration date or lot number. 8- Ammonium Hydroxide 28% Lot# 1732014 Received date 1/16/18 Label on bottle stated; Store locked up in well ventilated Space, but it was stored in regular cabinet under the counter top. 9- Richard -Allan Scientific Clarifier-1, label stated extremely flammable, was stored in regular cabinet. 10- Cytoseal 60 Lot# 263527 Expiration date 7/2015 11- Methyl Alcohol; 1 gallon Lot# 275029 Expiration date 12/2015 12- Protocol Formalin - 1:10 Dilution (Buffered) Lot# 280479 Expiration date 1/2018 Gallon bottles-3 13- Richard Allan Scientific clarifier 1 gallon Lot# 275257 Expiration date 10/2015 14- Dried Red marking ink; Davidson Marking System- Catalog # 1163-4 Dried Yellow marking ink; Davidson Marking System- Catalog # 1163-2 D- Flammable storage cabinet had hazardous chemicals, expired, not part of the laboratory, not labeled as not part of the laboratory. Interview with Histopathology and Cytology subspecialty laboratory director at about 4:45 PM, confirmed findings A to C; expired supplies in use in Histopathology and Cytology subspecialty laboratory. AND Finding D; Flammable storage cabinet had hazardous chemicals, expired, not part of the laboratory and not labeled as not part of the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation and interview laboratory failed to perform and record maintenance for fume hood filters and microscopes for the subspecialty of histopathology and cytology testing. Findings included: Laboratory tour on 4/9/18 at; 9:40AM showed; 1) FUMEGARD - activated carbon fume removal filter- date installed; 9/9/16 on the sticker, not functional. 2) SHANDON -- activated carbon fume removal filter- date installed; 9/9/16 on the sticker, functional. 3) FUMEGARD- no sticker as when was installed, functional. 4) Surgipath XYL -X50B air filter, no sticker to show when was installed, functional. 5) Only Surgipath XYL -X50B air filter was on at the time of investigation. 11:30AM showed; 5) Nikon microscope with no maintenance sticker. 4:00PM showed; 6) Nikon Labophot-2, serviced 12/15. 7) Olympus -BH-2, serviced 12/15. Besides the stickers on the filters for the dates installed, laboratory did not have any other maintenance records for review for the air filters. Besides the service sticker on the microscopes, there were no other microscope

	maintenance records for review. During an interview on 4/9/18 at I- 11:00AM, supervisor confirmed that; a) FUMEGARD - activated carbon fume removal filter- date installed; 9/9/16 on the sticker, was not functional, b) SHANDON -- activated carbon fume removal filter- date installed; 9/9/16 on the sticker, was functional, c) FUMEGARD-no sticker as when was installed, was functional, d) Surgipath XYL - X50B air filter, no sticker to show when was installed, was functional, e) there were no other maintenance records for the fume hood filters if the laboratory changed the filters after 9/9/16 to 4/9/18. f) SHANDON and FUMEGARD fume hood filters were kept on only at the time of specimen processing for the subspecialty of histopathology and cytology testing laboratory. g) Only Surgipath XYL -X50B air filter was on at the time of investigation. II-4:00 PM, supervisor confirmed that; A) Nikon microscope was not in use and not serviced. B) Laboratory did not service Nikon Labophot-2 and Olympus -BH-2 from year 2016 to 4/9/18 for the subspecialty of histopathology and cytology testing laboratory.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on laboratory procedure and policy for turnaround time for the test reporting, included in the Quality Assurance Program, and test report review, laboratory failed to follow the instructions for reporting the test result. Findings: 1- Requisition form, report and slide for patient #1, for PAP test (Papanicolaou test), reviewed on 4/10/18 showed specimen collection date and received date as 2/20/18 and the report date as 3 /5/18. There was no documentation or explanation for the delay in reporting of the test result. 2- Reviewed laboratory procedure and policy for turnaround time for the test reporting, included in the Quality Assurance Program on 4/10/18. As the cytology supervisor had to go for the day on 4/9/18, laboratory had provided the patient's test reports and the policy and procedure for the turnaround time for test report later via e-mail on 4/10/18, there was no interview with the supervisor.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the director and cytology

	supervisor, laboratory director failed to be responsible for overall operation and administration of the histology and cytology subspecialty testing laboratory, including the facility administration, general laboratory systems, pre-analytic systems, analytic systems, and post analytic systems and to establish and maintain the quality assessment program. Findings included: 1- No adequate space, required storage, and ventilation system that would properly remove vapors, fumes and excessive heat for the Histopathology and Cytology subspecialty laboratory chemicals. Refer to D3001. 2- No safety procedures observed to ensure protection from physical, chemical, biochemical, electrical hazards, and biohazardous materials. Refer to D3011. 3- Laboratory failed to document the correct collection date on the final report for hrHPV-DNA (high-risk Human Papilloma Virus- Deoxyribonucleic acid) test. Refer to D5203. 4- Laboratory had expired reagents in use. Refer to D5417. 5- No instruments maintenance performed for fume hood filters and microscopes for the subspecialty of histopathology and cytology testing. Refer to D5429. 6- Laboratory failed to follow policies and procedures for turnaround time for test reporting and to monitor, assess and correct problems in post analytic systems. Refer to D5891. 7- Laboratory failed to follow the policy and procedure, no corrective action, and no review of effectiveness of corrective action taken to resolve problems. Refer to D5293. On 4/9/18 at 4:45 PM laboratory director had confirmed the above findings 1 to 7.