Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0692983	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Umdc Dermatopathology Laboratory	1600 Nw 10th Ave Rmsb Rm 2055, Miami, 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	A recertification survey conducted on 9/04/2019 found that UMDC Dermopathology Laboratory, clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on competency assessment record review and staff interview, the laboratory failed to have annual assessment competencies that covered the six required procedure points for the testing personnel for 8 out of 9 testing personnel (TP) (TP# A, TP # B TP # C, TP # D, TP # E, TP # F, TP # G, TP # H) for 2 out 2 years reviewed. Findings include: Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 9/04/2019 revealed: a) Laboratory Director (LD) as Clinical Consultant, Technical Supervisor (TS) and TP # I b) 1 G S (also TP # A)) c) 7 TP (TP # B, TP # C, TP # D, TP # E, TP # F, TP # G, TP # H). Review of employee documentation provided during the inspection revealed the following: For TP A, B, C, D, E, F, G, H..; The laboratory failed to include the assessment of the TP in their laboratory activities. During a interview with GS, on 09/04/2019 at 2:30 PM, she confirmed that the competency assessment failed to evaluate the technical performance of the TP.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on user manual review and interview with testing personnel (TP)A, the laboratory failed to document room humidity requirement to assure optimal operation of the Tissue Tek VIP 6 AI, Automated Printing System for Tissue Cassettes (IPC) and Printer for slides (Leica IPS) for 2 out 2 years reviewed. Findings include: Review of Tissue Tek VIP 6 AI, installation guide manual revealed a room temperature range of 10 C to 40 C and humidity requirement not greater than 80 %. No documentation of the room temperature and humidity found for 2017, 2018 and 2019 (January to August). Review of IPS and IPC manuals revealed a room temperature range of 15 C to 25 C and humidity requirement not greater than 85 %. No documentation of the room temperature and humidity found for 2017, 2018 and 2019 (January to August). During an interview on 09/04/2019 at 2:30 p.m., the TP A confirmed that there was no record of room temperature and humidity control check for the rooms they were in use.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to have a negative control for immunohistochemical (IHC) stains for 59 out of 61 antibodies/panel each time of use. Findings include: Review of control IHC test menu revealed that: -The laboratory has in use 61 antibodies/panels for IHC, produced by Biocare, Beckton Dickinson, Leica, Santa Cruz Biotechnology, Cell Marque, Sigma, Abcam. -The laboratory used as negative control the internal components of the tissue that lack reactivity to the antigen for the following antibodies listed as per manufacturer: 1- Biocare: Berp4, Calponin-1 (EP63) Rabbit Monoclonal Antibody (P63), Treponema Pallidum rabbit polyclonal antibody (T.PALLIDUM), Pan Cytokeratine (AE1/AE3) 2- Becton Dickinson: Anti-Cytokeratin Purified. 3-Leica: BCL2, CD1a, CD2 (LFA-2), CD3, CD4, CD5, CD7, CD8, CD10, CD20, CD25, CD30, CD31 PECAM-1, CD34, CD45, CD68, CD79a, CD99, Carcinoembryonic Antigen (CEA), Cytokeratin 7 (CK7), Cytokeratin 20 (CK20), DESMIN, Epitelial membrane Antigen (EMA), HMB45, Von Willebrand Factor (FACTOR VIII-related Antigen), FACTOR XIII a, Cytokeratin (High Molecular Weight) KERATIN, Ki67, Micropthalmia Transcription Factor (MITF), Mast cell Tryptase (MAST CELL), Melan A (MART-1), MYELOPEROXIDASE, Neuron Specific Enolase (NSE), OSTEOPONTIN, p53 Protein (P53), Alpha Smooth Muscle Actin (SMA), S100, TTF-1, BCL-6

	Oncoprotein, SYNAPTOPHYSIN, CD138 (Syndecan-1), CD56 (NCAM) 4-Santa Cruz Biotechnology: ELAFIN antibody, 5-Cell Marque: HHV8, Herpes Simplex Virus I (10A3) Mouse Monoclonal Antibody (HSVI), Herpes Simplex Virus Rabbit Polyclonal Antibody (HSVII), Androgen Receptor (SP107) Rabbit Monoclonal Antibody (AR), Varicela Zoster Virus (VZV), CD99 (EPR3077Y) Rabbit Monoclonal Antibody (CD99), Collagen Type IV (CIV22) Mouse Monoclonal Antibody (Coll IV), SOX10 Rabbit Polyclonal Antibody (SOX10), CD117, C-Kit (YR145) Rabbit Monoclonal Antibody (CD117). 6-Sigma: Monoclonal anti-S100A6 antibody produced in mouse (S100 A6). 7-Abcam: Anti-osteopontin antibody (OSTEOPONTIN), anti-Tumor Necrosis Alpha TNF alpha antibody (TNF alpha). During an interview on 09/04/19 at 3:30 PM with the laboratory director, he confirmed that they use as negative control the areas were the antibody do not react with the tissue, except for the antibodies Estrogen Receptor (ER) and Progesterone Receptor (PR) used for breast cancer detection.