

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2173265	(X3) Date Survey Completed 07/20/2021
Name of Provider or Supplier Access Esperanza Clinics Inc	Street Address, City, State 916 E Hackberry Ave Suite B, Mcallen, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP) for testing performed on the GeneXpert analyzers, review of the laboratory's quality control records, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing at least every 30 days as required by its IQCP. The findings include: 1. A review of the laboratory's Individualized Quality Control Plans for its GeneXpert analyzers revealed the following: a) serial number: 834016 approved: 01/20/2020 "Controls will be tested</p>

at least every 30 days when testing patients." b) serial number: 834013 approved: 02/28/2021 "Controls will be tested at least every 30 days when testing patients." c) serial number: 834011 approved: 03/05/2020 "Controls will be tested at least every 30 days when testing patients." 2. A review of the laboratory's quality control records from January 2020 to June 2021 revealed the following instances when the elapsed time between quality control testing exceed 30 days and patient samples were tested: a) serial number: 834016 QC test date: 06/09/2020 Next QC test date: 07/28/2020 Elapsed time: 49 days QC test date: 03/18/2021 Next QC test date: 04/26/2021 Elapsed time: 39 days b) serial number: 834013 QC test date: 07/23/2020 Next QC test date: 08/31/2020 Elapsed time: 39 days c) serial number: 834811 QC test date: 08/05/2020 Next QC test date: 09/08/2020 Elapsed time: 34 days 3. A review of patient test records from the June 2020 to April 2021 revealed the following patients whose samples were tested on days when QC testing exceeded 30 days as required by the laboratory's IQCPs: a) serial number: 834016 07/10/2020 - 07/27/2021 Date Sample IDs 07/10 163012 07/10 155744 07/10 253461 07/10 213957 07/10 64964 07/10 254196 07/10 161544 07/10 242401 07/10 83545 07/10 125103 07/10 109412 07/10 260155 07/10 260156 07/10 83545 07/10 242471 07/10 98990 07/10 95211 07/13 250670 07/13 260175 07/13 121097 07/13 260168 07/13 260166 07/13 217756 07/13 244553 07/14 185255 07/14 229080 07/14 238714 07/14 113868 07/14 203774 07/14 252824 07/14 166183 07/14 106357 07/15 182747 07/15 237763 07/15 170667 07/15 249701 07/15 260209 07/15 237381 07/15 231534 07/15 253158 07/15 260206 07/16 260222 07/16 63415 07/16 103787 07/17 186419 07/17 260234 07/17 170631 07/17 241606 07/17 241762 07/17 208884 07/17 260245 07/17 240140 07/17 243178 07/17 245796 07/20 174149 07/20 243077 07/20 226445 07/20 260258 07/20 253948 07/20 160529 07/20 256666 07/20 260253 07/20 186726 07/20 170386 07/20 260250 07/20 179050 07/20 243162 07/20 178637 07/21 136536 07/21 260276 07/21 260271 07/21 241028 07/21 260265 07/21 171926 07/22 248418 07/22 149019 07/22 237623 07/22 249005 07/22 111852 07/22 182691 07/22 242908 07/22 242909 07/22 240481 07/22 246719 07/22 237595 07/23 91848 07/23 255695 07/24 121284 07/24 8069 07/24 212863 04/18/2021 - 04/25/2021 Date Sample ID 04/19 264041 04/19 170631 04/19 258926 04/19 258388 04/19 137221 04/19 241126 04/19 264030 04/19 145988 04/19 247696 04/20 264066 04/20 262231 04/20 243552 04/20 182349 04/20 234524 04/20 264052 04/20 184094 04/20 75167 04/21 140804 04/21 264094 04/21 186452 04/21 239793 04/21 190097 04/21 245997 04/22 264109 04/22 214796 04/22 248877 04/22 146026 04/22 143718 04/22 162202 04/23 115828 04/23 184967 04/23 255911 04/23 211296 04/23 155410 04/23 264114 04/23 165609 b) serial number: 834013 08/23/2020 - 08/30/2020 Date Sample ID 08/26 245996 08/26 249242 08/26 246602 08/26 209050 08/26 244401 08/26 254965 08/26 230429 08/26 238560 08/26 80081 08/26 223911 08/26 149653 08/27 169588 08/27 252455 08/27 116095 08/27 260733 08/27 253988 08/27 251343 08/28 260770 08/28 260769 08/28 251196 08/28 246673 08/28 193767 08/28 254219 08/28 245803 c) serial number: 834011 09/04/2020 - 09/07/2020 Date Sample ID 09/04 260872 09/04 205534 09/04 252467 09/04 137351 09/04 194728 4. The laboratory was asked to provide documentation of performing QC testing at the frequency stated in its IQCP. No documentation was provided. 5. An interview with the technical consultant on 07/20/2021 at 1230 hours in the conference room - after his review of the records- confirmed the findings. Key QC - quality control