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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br>BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR<br>MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES | <b>FEI:</b> 3007279191<br><b>DUNS:</b> 999999999<br><b>U.S. License Number:</b>   | <b>REASON FOR SUBMISSION</b><br>Annual Registration      | <b>DISTRICT OFFICE:</b> Dallas<br><b>VALIDATED BY FDA:</b> 12/23/2019 |
| <b>LEGAL NAME AND LOCATION:</b><br><br>QualTex Immunohematology Reference Laboratory<br>6211 IH 10 West at First Park Ten Blvd<br>San Antonio, TX 78201 USA<br><br>888-789-5227                                      | <b>REPORTING OFFICIAL:</b><br>Ward Carter<br>QualTex Immunohematology Reference Laboratory<br>6211 IH 10 West<br><br>San Antonio, TX 78201 USA<br>210-731-5508<br>ward.carter@qualtexlabs.org | <b>U.S. AGENT:</b>                                       |   |
| <b>OTHER NAMES USED IN THIS LOCATION:</b><br>QualTex Laboratories  | <b>TYPE OF OWNERSHIP:</b><br>CORPORATION<br><br><b>DONOR/RECIPIENT RELATIONSHIP:</b>  | <b>ESTABLISHMENT TYPE:</b><br>PRODUCT TESTING LABORATORY |   |

| PRODUCT                        | COLLECT | MANUAL APHERESIS | AUTOMATED APHERESIS | PREPARE | LEUKOCYTES REDUCED | IRRADIATED | DONOR RETESTED | TEST | STORE AND DISTRIBUTE TO OTHERS | BACTERIAL TESTING | PATHOGEN REDUCED | POOLED |
|--------------------------------|---------|------------------|---------------------|---------|--------------------|------------|----------------|------|--------------------------------|-------------------|------------------|--------|
| WHOLE BLOOD                    |         |                  |                     |         |                    |            |                | X    | X                              |                   |                  |        |
| RED BLOOD CELLS (RBC)          |         |                  |                     |         |                    |            |                | X    | X                              |                   |                  |        |
| RBC FROZEN                     |         |                  |                     |         |                    |            |                | X    |                                |                   |                  |        |
| RBC DEGLYCEROLIZED             |         |                  |                     |         |                    |            |                | X    | X                              |                   |                  |        |
| RBC REJUVENATED                |         |                  |                     |         |                    |            |                | X    |                                |                   |                  |        |
| RBC REJUVENATED FROZEN         |         |                  |                     |         |                    |            |                | X    |                                |                   |                  |        |
| RBC REJUVENATED DEGLYCEROLIZED |         |                  |                     |         |                    |            |                | X    |                                |                   |                  |        |
| CRYOPRECIPITATED AHF           |         |                  |                     |         |                    |            |                | X    | X                              |                   |                  |        |
| PLATELETS                      |         |                  |                     |         |                    |            |                | X    | X                              |                   |                  |        |
| GRANULOCYTES                   |         |                  |                     |         |                    |            |                | X    | X                              |                   |                  |        |

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| PRODUCT                              | COLLECT | MANUAL<br>APHERESIS | AUTOMATED<br>APHERESIS | PREPARE | LEUKOCYTES<br>REDUCED | IRRADIATED | DONOR<br>RETESTED | TEST | STORE AND<br>DISTRIBUTE<br>TO OTHERS | BACTERIAL<br>TESTING | PATHOGEN<br>REDUCED | POOLED |
|--------------------------------------|---------|---------------------|------------------------|---------|-----------------------|------------|-------------------|------|--------------------------------------|----------------------|---------------------|--------|
| PLASMA                               |         |                     |                        |         |                       |            |                   | X    | X                                    |                      |                     |        |
| FRESH FROZEN PLASMA                  |         |                     |                        |         |                       |            |                   | X    | X                                    |                      |                     |        |
| PLASMA CRYOPRECIPITATED REDUCED      |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |
| LIQUID PLASMA                        |         |                     |                        |         |                       |            |                   | X    | X                                    |                      |                     |        |
| THERAPEUTIC EXCHANGE PLASMA          |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |
| SOURCE LEUKOCYTES                    |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |
| SOURCE PLASMA                        |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |
| RECOVERED PLASMA                     |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |
| BLOOD PRODUCTS FOR DIAGNOSTIC<br>USE |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |
| BLOOD BANK REAGENTS                  |         |                     |                        |         |                       |            |                   | X    |                                      |                      |                     |        |

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|---------|---------|---------------------|------------------------|---------|-----------------------|------------|-------------------|------|--------------------------------------|----------------------|---------------------|--------|
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\*\*\*\*\* End Of Report \*\*\*\*\*