The NGSP has certified the following methods and reagents as having documented traceability to the Diabetes Control and Complications Trial Reference Method. Manufacturers are awarded Certificates of Traceability for successfully completing bias testing for specific methods, reagent lots, calibrator lots and instrumentation used. Traceability to the DCCT applies only to results from fresh blood samples. Analysis of processed (e.g. lyophilized) material may be subject to matrix effects and any comparisons to the DCCT using results from processed specimens should be made with caution.

The NGSP recommends that manufacturers certify their methods each year; the certificate of traceability expires after 1 year. During the year, it is the responsibility of the manufacturer to ensure that the results of their method remain consistent over time throughout the year and between lots. It is not the intent of the NGSP to certify each lot of reagents.

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<th>Manufacturer</th>
<th>Method/ Instrument</th>
<th>Method Type</th>
<th>Date Certified</th>
<th>Reagent Lot</th>
<th>Calibrator Lot</th>
<th>Calibrator Assigned Value</th>
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<tr>
<td>Shenzhen Labnovation Technologies, Inc.</td>
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<td>Ion-exchange HPLC</td>
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<td>Determiner L HbA1c on FUNOTEC FC-300</td>
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<td>Thermo Fisher Scientific Oy</td>
<td>HbA1c for Indiko, ref 981947, 981948 (91.5<em>HbA1c/Hb</em> +2.15)</td>
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<td>U911, U443</td>
<td>U386</td>
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<td>HbA1c for Konelab, ref 981947, 981948 (91.5<em>HbA1c/Hb</em> +2.15)</td>
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<td>UMA Co., Ltd</td>
<td>MEASURE HbA1c II on Hitachi 7180</td>
<td>Immunoassay</td>
<td>Mar ‘22</td>
<td>396ABA, 228ABA</td>
<td>134ABB</td>
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<td>HbA1c-FW on Hitachi 7180</td>
<td>Immunoassay</td>
<td>Mar ‘22</td>
<td>W22A201W</td>
<td>W21L011D</td>
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<td>W21A011D</td>
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<td>Boronate Affinity on Cera-Stat 4000 (Merilizer Mericheck Analyzer)</td>
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<td>Immunoassay on Skyla Hi Analyzer</td>
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<td>DxGen Corp.</td>
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<td>GuangDong Uniten Biotechnology Co., Ltd.</td>
<td>Turbidimetric inhibition immuno assay on Mindray BS-450</td>
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<td>3920211001, 3920211001H</td>
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<td>HPLC on CM-C1 Glycosylated Hemoglobin Analyzer</td>
<td>Ion-exchange HPLC</td>
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<td>HbA1c3 Colorimetric DxC600 Platform</td>
<td>Immunoassay</td>
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<td>M107745, M107745, M109385</td>
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<td>0.197, 0.455, 0.843, 1.481, 2.164 g/dL HbA1c; 19.19 g/dL Hb</td>
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<td>Ion-exchange HPLC</td>
<td>Jan '22</td>
<td>21026MDXH</td>
<td>21021MDXHC</td>
<td>5.40%, 9.80%</td>
<td>0021MDXHL</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>Human Gesellschaft für Biochemica und Diagnostica mbH</td>
<td>Ion-exchange HPLC on HumaNex A1c Variant</td>
<td>Ion-exchange HPLC</td>
<td>Jan '22</td>
<td>HAIC21026</td>
<td>HAIC210121</td>
<td>5.40%, 9.80%</td>
<td>02DSX21B23416</td>
<td>Zhongshan Hospital ASRL#2</td>
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<tr>
<td>Nihon Kohden Corporation</td>
<td>@Celltac Chemi HbA1c N on MEK-1303</td>
<td>Enzymo- assay</td>
<td>Jan '22</td>
<td>21013</td>
<td>CEN010</td>
<td>0.0%, 4.4%, 6.7%, 9.5%, 12.7%</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>@Celltac Chemi HbA1c N on CHM-4100</td>
<td>Enzymo- assay</td>
<td>Jan '22</td>
<td>21013</td>
<td>CEN010</td>
<td>0.0%, 4.4%, 6.7%, 9.5%, 12.7%</td>
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<td>ReCCS ASRL#1</td>
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<td>@Celltac Chemi HbA1c N on CHM-4100</td>
<td>Enzymo- assay</td>
<td>Jan '22</td>
<td>21048</td>
<td>CEN010</td>
<td>0.0%, 4.5%, 6.7%, 9.5%, 12.8%</td>
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<td>ReCCS ASRL#1</td>
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<td>i-SENS</td>
<td>Enzymatic on A1Care (also sold as Rapic L)</td>
<td>Enzymatic</td>
<td>Jan '22</td>
<td>DHHWAC</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>TaiDoc Technology Corp.</td>
<td>Immunoassay on TD-4611</td>
<td>Immuno- assay</td>
<td>Jan '22</td>
<td>21C112</td>
<td>130AAA</td>
<td>5.80%, 9.20%, 12.50%, 18.60%</td>
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<td>European Reference Lab ESRL#13</td>
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<td>Bio-Rad Laboratories</td>
<td>VARIANT II Dual (A1c)</td>
<td>Ion-exchange HPLC</td>
<td>Jan '22</td>
<td>64431428, 64431429, 64404588</td>
<td>64429485, 64429486</td>
<td>5.3%, 10.6%</td>
<td>GB60425 Univers of Missouri SRL #9</td>
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<td>VARIANT II Dual (A2/F/A1c)</td>
<td>Ion-exchange HPLC</td>
<td>Jan '22</td>
<td>64431428, 64431429, 64404588</td>
<td>64427344, 64429484</td>
<td>5.0%, 10.5%</td>
<td>GB60425 Univers of Missouri SRL #9</td>
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<td>Method/Instrument</td>
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<td>Calibrator Assigned Value</td>
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<td>Bio-Rad Laboratories</td>
<td>D-10 HbA1c</td>
<td>Ion-exchange HPLC</td>
<td>Jan '22</td>
<td>AA10352, AA10353, AA10298</td>
<td>AA10364, AA10365</td>
<td>5.4%, 10.5%</td>
<td>R90055D</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>D-10 HbA1c</td>
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<td>D-100 HbA1c</td>
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<td>D-10 Dual A2/F/A1c</td>
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<td>Variant II HbA1c NU</td>
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<td>VARIANT II TURBO HbA1c Kit – 2.0</td>
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<td>Lanson Biotechnology Co., Ltd.</td>
<td></td>
<td>Fluorescence Immunoassay on LS-1100</td>
<td>Dec '21</td>
<td>0012111 - - - Zhongshan Hospital ASRL#2</td>
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<td>Kinetic Diagnostic Industry</td>
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<td>Immunoturbidimetry on AU680</td>
<td>Dec '21</td>
<td>138819N, 138809N, 138208N</td>
<td>128145N</td>
<td>5.4%, 8.4%, 12.3%, 15.2%</td>
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<td>European Reference Lab ESRL#13</td>
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<td>Siemens Healthcare Diagnostics</td>
<td>Dimension A1C on ExL System</td>
<td>Immunoassay</td>
<td>Dec '21</td>
<td>GB2200</td>
<td>GB2200</td>
<td>0.18, 0.59, 1.11, 1.90, 2.62 g/dL HbA1c; 12.57, 12.17 g/dL Hb</td>
<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Dimension A1C on RxL System</td>
<td>Immunoassay</td>
<td>Dec '21</td>
<td>GB2200</td>
<td>GB2200</td>
<td>0.18, 0.59, 1.11, 1.90, 2.62 g/dL HbA1c; 12.57, 12.17 g/dL Hb</td>
<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Dimension A1C on Xpand System</td>
<td>Immunoassay</td>
<td>Dec '21</td>
<td>GB2200</td>
<td>GB2200</td>
<td>0.18, 0.59, 1.11, 1.90, 2.62 g/dL HbA1c; 12.57, 12.17 g/dL Hb</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</td>
<td>Enzymatic on BS2800M</td>
<td>Enzymatic</td>
<td>Dec '21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS600M</td>
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<td>Enzymatic on BS200E</td>
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<td>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</td>
<td>Enzymatic on BS240</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS240Pro</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>Enzymatic on BS360E</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>Enzymatic on BS380</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>Enzymatic on BS400</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS460 &amp; BS430</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS480</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS800 &amp; BS800M</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS830</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Enzymatic on BS2000 &amp; 2000M</td>
<td>Enzymatic</td>
<td>Dec ‘21</td>
<td>044621008</td>
<td>044621008</td>
<td>3.70, 14.8 µmol/L HbA1c; 93.8, 147 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Ion-exchange HPLC on H50/H50P</td>
<td>Ion-exchange HPLC</td>
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<td>Dec ‘21</td>
<td>2020120501, 2021071301, 2021071701</td>
<td>816RER-L, 816RER-H</td>
<td>5.09%, 11.00%</td>
<td>1D125M</td>
<td>ReCCS ASRL#1</td>
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<td>Roche Diagnostics International Ltd</td>
<td>Cobas HbA1c Test on cobas b 101</td>
<td>Immuno-assay</td>
<td>Dec ‘21</td>
<td>116131-01</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Roche Diagnostics</td>
<td>TQ HbA1c Gen. 3 Whole Blood on cobas c311</td>
<td>Immuno-assay</td>
<td>Dec ‘21</td>
<td>54387401, 55808901, 51941501</td>
<td>468538</td>
<td>0.128, 0.329, 0.652, 0.909, 1.242, 1.774 mmol/L HbA1c; 1.410, 7.602 mmol/L Hb</td>
<td>-</td>
<td>European Reference Lab ESRL#13</td>
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<td>Roche Diagnostics</td>
<td>TQ HbA1c Gen. 3 Whole Blood on cobas c303 HbA1c/Hb*91.5 +2.15</td>
<td>Immuno-assay</td>
<td>Dec '21</td>
<td>514339, 562669,</td>
<td>468538</td>
<td>0.152, 0.355, 0.680, 0.933, 1.282, 1.814 mmol/L HbA1c; 1.48, 7.98 mmol/L Hb</td>
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<td>European Reference Lab ESRL#13</td>
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<td>TQ HbA1c Gen. 3 Hemolysate on cobas c303 HbA1c/Hb*91.5 +2.15</td>
<td>Immuno-assay</td>
<td>Dec '21</td>
<td>514339, 562669, 521990</td>
<td>468538</td>
<td>0.149, 0.350, 0.668, 0.916, 1.258, 1.780 mmol/L HbA1c; 1.480, 7.980 mmol/L Hb</td>
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<td>European Reference Lab ESRL#13</td>
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<td>TQ HbA1c Gen. 3 Whole Blood on Cobas e111 HbA1c/Hb*91.5 +2.15</td>
<td>Immuno-assay</td>
<td>Dec '21</td>
<td>53930801, 54794401</td>
<td>468538</td>
<td>0.01597, 0.01065, 0.00761, 0.00532, 0.00266, 0.00106 mmol/L HbA1c; 0.07602, 0.05068, 0.03620, 0.02534, 0.01267, 0.00507 mmol/L Hb</td>
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<td>European Reference Lab ESRL#13</td>
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<td>OSANG Healthcare Co., Ltd.</td>
<td>Frontier and HemoCue HbA1c 501</td>
<td>Boronate Affinity</td>
<td>Nov ‘21</td>
<td>F21H11I01DL</td>
<td>-</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Clover A1c Plus</td>
<td>Boronate Affinity</td>
<td>Nov ‘21</td>
<td>B21F21G09EL</td>
<td>-</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Clover A1c, Clover A1c Self and Checkart</td>
<td>Boronate Affinity</td>
<td>Nov ‘21</td>
<td>A2101113EL</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Biosurfit, S.A.</td>
<td>spinit HbA1c test</td>
<td>Boronate Affinity</td>
<td>Nov ‘21</td>
<td>506_00</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>European Reference Lab ESRL#11</td>
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<td>Maccura Biotechnology Co., Ltd.</td>
<td>ion-exchange HPLC on maccura G01</td>
<td>ion-exchange HPLC</td>
<td>Nov ‘21</td>
<td>0721021</td>
<td>0721021</td>
<td>5.6%, 10.2%</td>
<td>20210401004</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>ACON Laboratories, Inc. and Acon Biotech (Hangzhou) Co., Ltd.</td>
<td>On Call MultiPro System—HbA1c</td>
<td>Immuno-assay</td>
<td>Oct ‘21</td>
<td>OGB1060 001, OGB1060 002, OGB1060 003</td>
<td>-</td>
<td>-</td>
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<td>Zhongshan Hospital ASRL#2</td>
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<td>Shenzhen New Industries Biomedical Engineering Co., Ltd (SNIBE)</td>
<td>Immoassay on Snibe Biolumi 8000</td>
<td>Immuno-assay</td>
<td>Oct ‘21</td>
<td>5512100101, 5512100101, 5512100101</td>
<td>5512100101</td>
<td>0.0%, 5.08%, 8.13%, 11.83%, 15.02%</td>
<td>-</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td></td>
<td>Immoassay on Snibe Biossay 240 Plus</td>
<td>Immuno-assay</td>
<td>Oct ‘21</td>
<td>5512100101, 5512100101, 5512100101</td>
<td>5512100101</td>
<td>0.0%, 5.08%, 8.13%, 11.83%, 15.02%</td>
<td>-</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>Immoassay on Snibe Biossay BC1200</td>
<td>Immuno-assay</td>
<td>Oct ‘21</td>
<td>5512100101, 5512100101, 5512100101</td>
<td>5512100101</td>
<td>0.0%, 5.08%, 8.13%, 11.83%, 15.02%</td>
<td>-</td>
<td>Zhongshan Hospital ASRL#2</td>
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<tr>
<td>Manufacturer</td>
<td>Method/Instrument</td>
<td>Method Type</td>
<td>Date Certified</td>
<td>Reagent Lot</td>
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<td>Calibrator Assigned Value</td>
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<td>Shenzhen New Industries Biomedical Engineering Co., Ltd (SNIBE)</td>
<td>Immunoassay on Hitachi LABOSPECT 008AS</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>5512100101, 5512100101, 5512100101</td>
<td>5512100101</td>
<td>0.0%, 0.08%, 8.13%, 11.83%, 15.02%</td>
<td>-</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>Ailex Technology Group Co., Ltd.</td>
<td>Ion-exchange HPLC on AH-600</td>
<td>Ion-exchange HPLC</td>
<td>Oct ‘21</td>
<td>210403AA1, 210403AA2, 210403AA3, 21070801</td>
<td>Y/20210630, Y/20210630</td>
<td>5.83%, 10.53%</td>
<td>2103A0038</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>JEOL Ltd.</td>
<td>BM Test HbA1c on JCA-BM6010/C</td>
<td>Enzymatic</td>
<td>Oct ‘21</td>
<td>955RDS, 956RDS, 852RLR</td>
<td>931RDS</td>
<td>3.68, 14.56 µmol/L; HbA1c: 99.3, 155.4 µmol/L</td>
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<td>ReCCS ASRL#1</td>
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<td>HORIBA Medical</td>
<td>Spotchem Banalyst HbA1c on SI-3620</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>2132JB048O</td>
<td>WC0063</td>
<td>0.0, 25.5, 83.5, 122.9 mmol/mol</td>
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<td>ReCCS ASRL#1</td>
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<td>Banalyst Ace HbA1c on Banalyst Ace</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>2132JB049A</td>
<td>WC0063</td>
<td>0.0, 25.5, 83.5, 122.9 mmol/mol</td>
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<td>ReCCS ASRL#1</td>
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<td>Spotchem Banalyst HbA1c on SI-3610</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>2132JB048O</td>
<td>WC0063</td>
<td>0.0, 25.5, 83.5, 122.9 mmol/mol</td>
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<td>ReCCS ASRL#1</td>
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<td>Banalyst HbA1c on Yumizen M100 Banalyst</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>2132JB049A</td>
<td>WC0063</td>
<td>0.0, 25.5, 83.5, 122.9 mmol/mol</td>
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<td>ReCCS ASRL#1</td>
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<td>Shijiazhuang Hipro Biotechnology Co., Ltd</td>
<td>Nephelometry on HP-083/4 II POCT Immunoassay System</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>FA210722</td>
<td>S3519-4, S3519-4, S3519-4, S3519-4, S3519-4, S3519-4</td>
<td>0.0%, 2.4%, 4.8%, 8.5%, 12.2%, 15.6%</td>
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<td>Zhongshan Hospital ASRL#2</td>
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<td>Nephelometry on HP-AFS/1 Automatic Immunoassay Analyzer</td>
<td>Immunoassay</td>
<td>Oct ‘21</td>
<td>FA210722</td>
<td>S3519-4, S3519-4, S3519-4, S3519-4, S3519-4, S3519-4</td>
<td>0.0%, 2.4%, 4.8%, 8.5%, 12.2%, 15.6%</td>
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<td>Zhongshan Hospital ASRL#2</td>
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<td>DiaSys Diagnostic Systems GmbH</td>
<td>oneHbA1c IS on InnovaStar HbA1c (NGSP) = 0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept ‘21</td>
<td>123, 29743</td>
<td>28963, 28964, 28965, 28966</td>
<td>30.8, 63.2, 116, 151 mmol/mol</td>
<td>-</td>
<td>European Reference Lab ESRL#10</td>
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<td>HbA1c net FS with onboard hemolysis on JCA-BM6010/C HbA1c (NGSP) = 0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept ‘21</td>
<td>30371, 29528</td>
<td>31667, 31667</td>
<td>0.425, 1.08 g/dL HbA1c; 7.80, 15.5 g/dL Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<td>HbA1c net FS with onboard hemolysis on Sysmex BX-3010 HbA1c (NGSP) = 0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept ‘21</td>
<td>30371, 29528</td>
<td>30073, 30073</td>
<td>0.466, 1.21 g/dL HbA1c; 5.02, 15.0 g/dL Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<td>DiaSys Diagnostic Systems GmbH</td>
<td>HbA1c net FS with onboard hemolysis on Respons910 HbA1c (NGSP) =0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept’21</td>
<td>30371, 29528</td>
<td>31667, 31667</td>
<td>0.425, 1.08 g/dL HbA1c; 7.80, 15.5 g/dL Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<td>HbA1c net FS with manual hemolysis on JCA-BM6010/C HbA1c (NGSP) =0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept’21</td>
<td>30371, 29528</td>
<td>31667, 31667</td>
<td>0.465, 1.20 g/dL HbA1c; 6.80, 15.0 g/dL Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<td>oneHbA1c FS, 2 components on JCA-BM6010/C HbA1c (NGSP) =0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept’21</td>
<td>29845-47, 27953</td>
<td>31467, 31468</td>
<td>29.3, 52.0, 122, 147 mmol/mol</td>
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<td>European Reference Lab ESRL#10</td>
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<td>oneHbA1c FS, 2 components on respons920 HbA1c (NGSP) =0.0915xHbA1c (IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Sept’21</td>
<td>29845-47, 27953</td>
<td>31467, 31468</td>
<td>29.3, 52.0, 122, 147 mmol/mol</td>
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<td>Super-ID HbA1c on SUPER ID clinchem</td>
<td>Enzymatic</td>
<td>Sept’21</td>
<td>123, 29743</td>
<td>28963, 28965</td>
<td>30.8, 63.2, 116, 151 mmol/mol</td>
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<td>European Reference Lab ESRL#10</td>
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<td>Erba Lachema s.r.o.</td>
<td>ERBA Hb-Vario</td>
<td>Ion-exchange HPLC</td>
<td>Sept ’21</td>
<td>2003167, 2003167</td>
<td>2003167L1, 2003167L2</td>
<td>5.44%, 12.90%</td>
<td>2003167</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Horiba Medical</td>
<td>HbA1c WB Hemolysate – ABX Pentra C200 (Y=(0.2654*X) +2.229)</td>
<td>Immuno-assay</td>
<td>Sept ’21</td>
<td>2101601</td>
<td>2100100</td>
<td>0.00, 1.85, 3.56, 5.26, 9.28, 14.40 µmol/L HbA1c; 68.29 µmol/L Hb</td>
<td>-</td>
<td>European Reference Lab ESRL#10</td>
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<tr>
<td></td>
<td>HbA1c WB Whole Blood – ABX Pentra 400 (Y=(0.3275*X) +2.367)</td>
<td>Immuno-assay</td>
<td>Sept ’21</td>
<td>2101601</td>
<td>2100100</td>
<td>0.00, 1.81, 3.57, 5.31, 9.62, 15.22 µmol/L HbA1c; 68.29 µmol/L Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<td>HbA1c WB Hemolysate – ABX Pentra 400 (Y=(0.3493*X) +1.868)</td>
<td>Immuno-assay</td>
<td>Sept ’21</td>
<td>2101601</td>
<td>2100100</td>
<td>0.00, 2.22, 3.72, 5.22, 8.98, 13.84 µmol/L HbA1c; 68.29 µmol/L Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<tr>
<td>Horiba Medical</td>
<td>HbA1c WB Hemolysate – ABX Pentra C400 (Y=(0.3865*X) +2.334)</td>
<td>Immuno-assay</td>
<td>Sept ’21</td>
<td>2101601</td>
<td>2100100</td>
<td>0.00, 1.53, 3.04, 4.39, 7.76, 12.30 µmol/L HbA1c; 68.29 µmol/L Hb</td>
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<td>European Reference Lab ESRL#10</td>
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<td>Method/Instrument</td>
<td>Method Type</td>
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<td>Calibrator Assigned Value</td>
<td>Column Lot</td>
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<tr>
<td>Horiba Medical</td>
<td>HbA1c WB</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>2101601</td>
<td>2100101</td>
<td>0.00, 1.47, 3.19, 4.73, 8.55, 13.70 µmol/L HbA1c; 68.29 µmol/L Hb</td>
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<td>EKF Diagnostics GmbH</td>
<td>^1 Boronate-Affinity Quo-Test HbA1C</td>
<td>Boronate affinity</td>
<td>Sept '21</td>
<td>020625</td>
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<td>European Reference Lab ESRL #11</td>
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<td>Human Gesellschaft fuer Biochemica und Diagnostica mbH</td>
<td>^2 Boronate-Affinity Quo-Lab HbA1C</td>
<td>Boronate affinity</td>
<td>Sept '21</td>
<td>025935</td>
<td>-</td>
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<td>European Reference Lab ESRL #11</td>
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<tr>
<td>Agappe Diagnostics Ltd.</td>
<td>^3Nephelometry on Specific Protein Analyzer Mispa i2</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
<td>-</td>
<td>European Reference Lab ESRL #10</td>
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<td>^4Nephelometry on cartridge based Specific Protein Analyzer Mispa i3</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
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<td>European Reference Lab ESRL #10</td>
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<td>^5AgA1c (Immunoturbidimetric method) on TMS 30i</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
<td>-</td>
<td>European Reference Lab ESRL #10</td>
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<td>^6AgA1c (Immunoturbidimetric method) on TBA-120FR</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
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<td>European Reference Lab ESRL #10</td>
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<td>^7AgA1c (Immunoturbidimetric method) on TBA-25FR</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
<td>-</td>
<td>European Reference Lab ESRL #10</td>
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<td>^8AgA1c (Immunoturbidimetric method) on Turbiquick</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
<td>-</td>
<td>European Reference Lab ESRL #10</td>
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<td>^9AgA1c (Immunoturbidimetric method) on Mispa Viva</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
<td>-</td>
<td>European Reference Lab ESRL #10</td>
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<td>^10AgA1c (Immunoturbidimetric method) on Mispa Plus</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
<td>-</td>
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<td>^11AgA1c (Immunoturbidimetric method) on Mispa CCXL</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>6.50%, 10.20%, 14.50%, 17.00%</td>
<td>-</td>
<td>European Reference Lab ESRL #10</td>
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<td>^12AgA1c (Immunoturbidimetric method) on Mispa CX4</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>6.50%, 10.20%, 14.50%, 17.00%</td>
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<td>European Reference Lab ESRL #10</td>
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<td>Manufacturer</td>
<td>Method/Instrument</td>
<td>Method Type</td>
<td>Date Certified</td>
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<td>Agappe Diagnostics Ltd...</td>
<td>1AgA1c (Immunoturbidimetric method) on Mispa CXL Pro</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
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<td>European Reference Lab ESRL#10</td>
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<td>1AgA1c (Immunoturbidimetric method) on Mispa Clinia Plus</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
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<td>European Reference Lab ESRL#10</td>
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<td>1AgA1c (Immunoturbidimetric method) on BS 390</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>5.70%, 10.10%, 13.40%, 16.00%</td>
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<td>1AgA1c (Immunoturbidimetric method) on Mispa Clinia</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>6.30%, 10.30%, 14.40%, 17.30%</td>
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<td>1AgA1c (Immunoturbidimetric method) on Mispa Nano</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>6.30%, 10.30%, 14.40%, 17.30%</td>
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<td>1AgA1c (Immunoturbidimetric method) on Mispa Nano Plus</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>6.30%, 10.30%, 14.40%, 17.30%</td>
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<td>1AgA1c (Immunoturbidimetric method) on Mispa Ace</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>41050770, 41050771, 11070081</td>
<td>41050370, 41050371, 41050372, 41050373</td>
<td>6.30%, 10.30%, 14.40%, 17.30%</td>
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<td>European Reference Lab ESRL#10</td>
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<td>Apex Biotechnology Corp.</td>
<td>Immunoagglutination on Eclipse A1c</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>S10501</td>
<td>-</td>
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<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>Everly Diagnostics</td>
<td>Red blood cell-serum strip-based cassettes on Beckman B00389 AU680</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>M104559, 1052B</td>
<td>1052</td>
<td>0.219, 0.456, 0.848, 1.529, 2.214 mmol/L HbA1c; 13.53 mmol/L Hb</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Minaris Medical Co., Ltd.</td>
<td>MetaboLead HbA1c on DM-JACK</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>413AAE, 413AAE</td>
<td>501AIF</td>
<td>2.49, 9.56 µmol/L HbA1c; 82.6, 119.2 µmol/L Hb</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>MetaboLead HbA1c on JCA-BM9130</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>413AAE, 413AAE</td>
<td>501AIF</td>
<td>2.49, 9.56 µmol/L HbA1c; 82.6, 119.2 µmol/L Hb</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>MetaboLead HbA1c on Hitachi 7180</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>413AAE, 413AAE</td>
<td>501AIF</td>
<td>2.49, 9.56 µmol/L HbA1c; 82.6, 119.2 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>MetaboLead HbA1c on LABOSPECT 006</td>
<td>Immunoassay</td>
<td>Sept '21</td>
<td>413AAE, 413AAE</td>
<td>501AIF</td>
<td>2.49, 9.56 µmol/L HbA1c; 82.6, 119.2 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>Manufacturer</td>
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<td>Calibrator Assigned Value</td>
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<td>Minaris Medical Co., Ltd.</td>
<td>MetaboLead HbA1c on TBA-120FR</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>413AAE, 413AAE</td>
<td>501AAF</td>
<td>2.49, 9.56 µmol/L HbA1c; 82.6, 119.2 µmol/L Hb</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>Aspen Laboratories Pvt. Ltd.</td>
<td>Nephelometry on NEPH</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>NEPHG062101</td>
<td>-</td>
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<td>European Reference Lab ESRL#10</td>
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<td>Fluorescence Immunoassay on FIA</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>FIAW062101</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>European Reference Lab ESRL#10</td>
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<td>Furuno Electric Co. Ltd.</td>
<td>Centronic HbA1c Turbidimetric immunoassay on CA-800</td>
<td>Immuno-assay</td>
<td>Sept '21</td>
<td>HF0421G1-107, HF0421G1-107, HF0421GLY-107,</td>
<td>111001</td>
<td>0%, 5.4%, 8.7%, 11.8%, 16.0%</td>
<td>-</td>
<td>ReCCS ASRL#1</td>
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<td>Hunan Yonghe-Sun Biotechnology Co., Ltd.</td>
<td>Ion-exchange HPLC on YH-30 Glycohemoglobin Analyzer</td>
<td>Ion-exchange HPLC</td>
<td>Aug '21</td>
<td>20210105, 20210323</td>
<td>20210526, 20210526</td>
<td>5.60%, 9.40%</td>
<td>20210323</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>MED TRUST Handelsges.m.b.H.</td>
<td>Boronate Affinity on WellIon BONA HbA1c</td>
<td>Boronate affinity</td>
<td>Aug '21</td>
<td>EAG210406081</td>
<td>-</td>
<td>-</td>
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<td>Boronate Affinity on WellIon CLEVER HbA1c</td>
<td>Boronate affinity</td>
<td>Aug '21</td>
<td>EAZ210302011</td>
<td>-</td>
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<td>Zhongshan Hospital ASRL#2</td>
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<td>Sugentech</td>
<td>Immunooassay on INCLIX</td>
<td>Immunooassay</td>
<td>Aug '21</td>
<td>HBAT21002</td>
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<td>ReCCS ASRL#1</td>
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<td>Beckman Coulter Ireland Inc.</td>
<td>HbA1c Advanced B93009 Online Application on DxC700 AU</td>
<td>Immuno-assay</td>
<td>Aug '21</td>
<td>1053, 472137</td>
<td>1053</td>
<td>0.098, 0.287, 0.539, 0.999, 1.398 mmol/L HbA1c; 9.00 mmol/L Hb</td>
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<td>European Reference Lab ESRL#13</td>
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<td>HbA1c Advanced B00389 Manual Application on DxC700 AU</td>
<td>Immuno-assay</td>
<td>Aug '21</td>
<td>1053, 472137</td>
<td>1053</td>
<td>0.112, 0.287, 0.514, 0.972, 1.428 mmol/L HbA1c; 9.00 mmol/L Hb</td>
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<td>Immuno-assay</td>
<td>Aug '21</td>
<td>1053, 472137</td>
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<td>0.112, 0.287, 0.514, 0.972, 1.428 mmol/L HbA1c; 9.00 mmol/L Hb</td>
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<td>HbA1c Advanced B00389 Manual Application on AU5800</td>
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<td>1053, 472137</td>
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<td>0.112, 0.287, 0.514, 0.972, 1.428 mmol/L HbA1c; 9.00 mmol/L Hb</td>
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<td>Aug '21</td>
<td>1053, 472137</td>
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<td>0.112, 0.287, 0.514, 0.972, 1.428 mmol/L HbA1c; 9.00 mmol/L Hb</td>
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<td>Ortho Clinical Diagnostics</td>
<td>VITROS Chemistry Products A1c Slides on VITROS XT 7600 Integrated System</td>
<td>Enzymatic</td>
<td>Aug '21</td>
<td>0103</td>
<td>3302</td>
<td>3.00%, 5.41%, 10.60%</td>
<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>VITROS</td>
<td>VITROS Chemistry Products A1c Slides on VITROS 5600 Integrated System</td>
<td>Enzymatic</td>
<td>Aug '21</td>
<td>0103</td>
<td>3302</td>
<td>2.96%, 5.27%, 10.61%</td>
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<td>VITROS</td>
<td>VITROS Chemistry Products A1c Slides on VITROS XT 3400 Chemistry System</td>
<td>Enzymatic</td>
<td>Aug '21</td>
<td>0103</td>
<td>3302</td>
<td>3.00%, 5.41%, 10.60%</td>
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<td>Shenzhen Microprofit Biotech Co., Ltd.</td>
<td>Immunofluorescence chromatograph on MF-T1000 Dry-Type Immunofluorescence Quantitative Analyzer</td>
<td>Immunoassay</td>
<td>Aug '21</td>
<td>20210501, 20210502, 20210503, 20210501101, 20210501102, 20210501103</td>
<td>20210501, 20210502, 20210503</td>
<td>6.53%, 9.51%; 6.50%, 9.52%; 6.51%, 9.49%</td>
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<td>Zhongshan Hospital ASRL#2</td>
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<td>JW Bioscience</td>
<td>Immunoassay on JCA-BM6010/C</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>102</td>
<td>Cal102</td>
<td>5.6%, 8.3%, 11.6%, 15.5%</td>
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<td>Boditech Med Inc.</td>
<td>Immuno-assay on AFIAS-1</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>AARDB46F</td>
<td>929601</td>
<td>5.1%, 7.18%, 9.71%, 12.53%</td>
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<td>Immuno-assay on AFIAS-6</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>AARDB46F</td>
<td>929601</td>
<td>5.1%, 7.18%, 9.71%, 12.53%</td>
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<td>Immuno-assay on AFIAS-10</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>AARDB46F</td>
<td>929601</td>
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<td>Immuno-assay on ichroma Reader</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>AAREL07</td>
<td>929601</td>
<td>5.4%, 7.4%, 10.4%, 13.5%</td>
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<td>Immuno-assay on ichroma II</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>AAREL07</td>
<td>929601</td>
<td>5.4%, 7.4%, 10.4%, 13.5%</td>
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<td>Immuno-assay on ichroma III</td>
<td>Immunoassay</td>
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<td>AAREL07</td>
<td>929601</td>
<td>5.4%, 7.4%, 10.4%, 13.5%</td>
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<td>Getein Biotech, Inc.</td>
<td>Immunofluorescence Assay on Getein 1100</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>YBC210105</td>
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<td>Immunofluorescence Assay on Getein 1600</td>
<td>Immunoassay</td>
<td>July '21</td>
<td>P009210004</td>
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<td>Getein Biotech, Inc.</td>
<td>Colloidal Gold on FIA8600/8000</td>
<td>Immuno- assay</td>
<td>July '21</td>
<td>6BC210017</td>
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<td>Immuno-fluorescence Assay on Getein 1180</td>
<td>Immuno- assay</td>
<td>July '21</td>
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<td>Instrumentation Laboratory</td>
<td>HbA1c Enzymatic (Manual pretreatment) on Ilab Taurus</td>
<td>Enzymatic</td>
<td>July '21</td>
<td>I0221024</td>
<td>I0221025, I0221025</td>
<td>3.16, 13.93 µmol/L HbA1c; 96.1, 146.4 µmol/L Hb</td>
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<td>European Reference Lab ESRL#16</td>
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<td>Wells Bio, Inc.</td>
<td>Boronate Affinity on careSURE Analyzer 100</td>
<td>Boronate Affinity</td>
<td>July '21</td>
<td>BHB21B151, BHB21B231</td>
<td>10207053, 10207033</td>
<td>3.16, 13.93 µmol/L HbA1c; 96.1, 146.4 µmol/L Hb</td>
<td>-</td>
<td>ReCCCS ASRL#1</td>
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<td>J. Mitra &amp; Co. Pvt Limited</td>
<td>Fluorescence immunoassay on i-Quant Analyzer</td>
<td>Immuno- assay</td>
<td>July '21</td>
<td>HBQ/XI/030 321</td>
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<td>Greencross Medical Science</td>
<td>Boronate Affinity on Greencare A1c</td>
<td>Boronate Affinity</td>
<td>July '21</td>
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<td>Boronate Affinity on Arkay Pocket Chem A1c Advanced</td>
<td>Boronate Affinity</td>
<td>July '21</td>
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<td>Boronate Affinity on Diasys India QDx A1c Advance</td>
<td>Boronate Affinity</td>
<td>July '21</td>
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<td>Boronate Affinity on Medisys Hemo G Smart Analyzer</td>
<td>Boronate Affinity</td>
<td>July '21</td>
<td>R11C041</td>
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<td>Qurasense, Inc.</td>
<td>Qvin Q-Pad HbA1c Test using Qvin Q-Pad HbA1c Test Strip on AU480</td>
<td>Immuno- assay</td>
<td>July '21</td>
<td>1051, M101040, 85810</td>
<td>1051</td>
<td>0.114, 0.450, 0.876, 1.498, 2.333 g/dL HbA1c; 0, 14.58 g/dL Hb</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Chiangsha Sinocare Inc.</td>
<td>HbA1c Monitoring System on PCH-100</td>
<td>Immuno- assay</td>
<td>July '21</td>
<td>1A0425</td>
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<td>HbA1c Monitoring System on PCH-50</td>
<td>Immuno- assay</td>
<td>July '21</td>
<td>12K0330</td>
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<td>HbA1c Monitoring System on iCARE-2000</td>
<td>Immuno- assay</td>
<td>July '21</td>
<td>11P0331</td>
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<td>Chiangsha Sinocare Inc.</td>
<td>HbA1c Monitoring System on iCARE-2100</td>
<td>Immuno-assay</td>
<td>July '21</td>
<td>11P0331</td>
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<td>HbA1c Monitoring System on A1CNow+</td>
<td>Immuno-assay</td>
<td>July '21</td>
<td>2017723</td>
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<td>HbA1c Monitoring System on A1CNow Self Check</td>
<td>Immuno-assay</td>
<td>July '21</td>
<td>200861</td>
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<td>Intelligene Biosystems (Qingdao) Co., Ltd</td>
<td>Matrix-Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry (MALDI-TOF-MS) on Quan TOF I</td>
<td>MALDI-TOF-MS</td>
<td>July '21</td>
<td>20201125-001; 20201125-001</td>
<td>R2-lot: 202021125-001; R-4Lot: 20201125-001</td>
<td>6.11%, 10.93%</td>
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<td>Wuxi Biohermes Bio &amp; Medical Technology Co., Ltd.</td>
<td>Boronate Affinity on A1C EZ 2.0 Glycohemoglobin Analysis System</td>
<td>Boronate Affinity</td>
<td>July '21</td>
<td>EAP210507041</td>
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<td>Boronate Affinity on A1cChek Express Glycohemoglobin Analysis System</td>
<td>Boronate Affinity</td>
<td>July '21</td>
<td>CAZ210302041</td>
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<td>Boronate Affinity on A1cChek Pro Glycohemoglobin Analysis System</td>
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<td>July '21</td>
<td>CAW210512031</td>
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<td>Ion-exchange HPLC on BH60 Automatic Glycohemoglobin Analysis System</td>
<td>Ion-exchange HPLC</td>
<td>July '21</td>
<td>CHH21032901AA</td>
<td>CHW21030901</td>
<td>5.13%, 10.45%</td>
<td>CHD21410002AA</td>
<td>Zhongshan Hospital ASRL#2</td>
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<td>Boronate Affinity on GluCoA1c Blood Glucose and Glycohemoglobin Analysis System</td>
<td>Boronate Affinity</td>
<td>July '21</td>
<td>CAE210525081</td>
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<td>Sebia</td>
<td>Capillaries HbA1c on Capillaries 2 Flex Piercing %NGSP=0.0914 8 x [IFCC] (mmol/mol) + 2.152</td>
<td>Capillary Electrophoresis</td>
<td>June '21</td>
<td>08108/01, 30010/01, 08060/01</td>
<td>05030/01, 06030/01</td>
<td>35.8, 85.9 mmol/mol</td>
<td>-</td>
<td>European Reference Lab ESRL#10</td>
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<td>Minicap HbA1c %NGSP=0.0914 8 x [IFCC] (mmol/mol) + 2.152</td>
<td>Minicap HbA1c Capillary Electrophoresis</td>
<td>June '21</td>
<td>07120/01, 31108/01, 23049/01</td>
<td>05030/01, 06030/01</td>
<td>35.8, 85.9 mmol/mol</td>
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<td>European Reference Lab ESRL#10</td>
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<td>Sebia</td>
<td>CAPI 3 HbA1c on Capillaries 3</td>
<td>Capillary Electrophoresis</td>
<td>June ’21</td>
<td>20040/01, 31110/01, 08060/01</td>
<td>13069/01, 14069/01</td>
<td>37.0, 87.8 mmol/mol</td>
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<td>European Reference Lab ESRL#10</td>
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<td>Human Gesellschaft fur Biochemica und Diagnostica GmbH</td>
<td>HumanNex A1c</td>
<td>Ion-exchange HPLC</td>
<td>June ’21</td>
<td>210222, 210222, 210222</td>
<td>20201124, 20201124</td>
<td>5.75%, 11.05%</td>
<td>210222</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Shanghai Medconn Medical Technology Co. Ltd (China)</td>
<td>HPLC on MQ-2000PT</td>
<td>Ion-exchange HPLC</td>
<td>June ’21</td>
<td>PTHbA1c20 112C, PTHbA1c20 112C, PTHbA1c20 112C</td>
<td>20210113, 20210113</td>
<td>5.71%, 11.04%</td>
<td>PTHbA1c20 1112C</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>HPLC on MQ-6000</td>
<td>Ion-exchange HPLC</td>
<td>June ’21</td>
<td>20201109I, 20201109I, 20201109I</td>
<td>20210113, 20210113</td>
<td>5.65%, 10.82%</td>
<td>20201109I</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>HPLC on MQ-8000</td>
<td>Ion-exchange HPLC</td>
<td>June ’21</td>
<td>20201130H, 20201130H, 20201130H</td>
<td>20210113, 20210113</td>
<td>5.56%, 10.88%</td>
<td>20201130H</td>
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<td>HPLC on MQ-8000PT</td>
<td>Ion-exchange HPLC</td>
<td>June ’21</td>
<td>20200907H, 20200907H, 20200907H</td>
<td>20210113, 20210113</td>
<td>5.51%, 10.72%</td>
<td>20200907H</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>Latex agglutination on AU5800</td>
<td>Immuno-assay</td>
<td>June ’21</td>
<td>02Hba1c21 0127</td>
<td>201027, 201027, 201027, 201027</td>
<td>0.0%, 5.5%, 9.5%, 13.5%, 17.7%</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Goldsite Diagnostics Inc.</td>
<td>HbA1c on GSH-60</td>
<td>Ion-exchange HPLC</td>
<td>June ’21</td>
<td>910001210315, 910002210315, 910003210315</td>
<td>20210407, 20210407</td>
<td>5.60%, 10.60%</td>
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<td>Zhongshan Hospital ASRL#2</td>
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<td>HbA1c on Aristo</td>
<td>Immuno-assay</td>
<td>June ’21</td>
<td>0572220510, 0572220510, 0572220510, 0572220510</td>
<td>ALO3819, ALO3819, ALO3819, ALO3819</td>
<td>5.30%, 8.00%, 11.00%, 15.50%</td>
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<td>HbA1c on GPP-100</td>
<td>Immuno-assay</td>
<td>June ’21</td>
<td>1072200401, 1072200401, 1072200401</td>
<td>ALO3819, ALO3819, ALO3819, ALO3819</td>
<td>5.30%, 8.00%, 11.00%, 15.50%</td>
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<td>Ortho Clinical Diagnostics</td>
<td>%A1c on Vitros 5,1 FS</td>
<td>Immuno-assay</td>
<td>June ’21</td>
<td>8245</td>
<td>3170</td>
<td>0.165, 0.885, 1.795, 3.996 g/dL HbA1c; -0.641, 3.049, 7.372, 16.155 g/dL Hb</td>
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<td>%A1c on Vitros 4600</td>
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<td>0.171, 0.887, 1.781, 3.958 g/dL HbA1c; -0.641, 3.049, 7.372, 16.155 g/dL Hb</td>
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<td>Immuno-assay</td>
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<td>Roche Diagnostics GmbH</td>
<td>TQ HbA1c Gen. 3 on cobas c 501 / c 502 (HbA1c/Hb*91. 5+2.15)</td>
<td>Immuno-assay</td>
<td>June ‘21</td>
<td>488850, 519415, 531374</td>
<td>468538</td>
<td>0.136, 0.348, 0.690, 0.962, 1.315, 1.879 mmol/L HbA1c; 1.410, 7.602 mmol/L Hb</td>
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<td>TQ HbA1c Gen. 3 Hemolysate on cobas c503 (HbA1c/Hb*91. 5+2.15)</td>
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<td>459182, 521990, 488873</td>
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<td>0.144, 0.338, 0.646, 0.885, 1.217, 1.721mmol/L HbA1c; 1.48, 7.98 mmol/L Hb</td>
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<td>Tosoh Corporation</td>
<td>1G7 HbA1c Standard Analysis Mode (1.2 min) HLC-723G7</td>
<td>Ion-exchange</td>
<td>June ‘21</td>
<td>P7-101E, P7-201E, 7-302E, HW-42E</td>
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| Univ. of Missouri. SRL #9 |

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<td>'G8 HbA1c Standard Analysis Mode Ver. 5.29 (1.0 min) HLC-723G8</td>
<td>Ion-exchange HPLC</td>
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<td>R8-106F, R8-205F, S8-302F, HW-19F</td>
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<td>'G9 HbA1c, HLC-723G9, Ver. 1.10</td>
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<td>D9-102F, D9-201F, S8-301F, HW-19F</td>
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<td>G8 HbA1c</td>
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<td>S8-101F, S8-201F, S8-301F, HW-19F</td>
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<td>5.95%, 10.31%</td>
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<td>5.95%, 10.31%</td>
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<td>5.95%, 10.31%</td>
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<td>Jiangsu Audicomm Medical Technology Co., Ltd.</td>
<td>Ion-exchange chromatography on AC6601</td>
<td>Ion-exchange HPLC</td>
<td>June '21</td>
<td>210201-20, 210201-21, 210201-22, 210201-23, 210201-24</td>
<td>210201-26, 210201-27</td>
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<td>Arkray, Inc.</td>
<td>t CinQ HbA1c on JCA-BM9130 HbA1c%(NGSP) = 0.0915<em>HbA1c/Hb</em>1000(IFC C) + 2.15</td>
<td>Enzymatic</td>
<td>May '21</td>
<td>MFA19, MFE20</td>
<td></td>
<td>2.73, 6.94 µmol/L HbA1c; 95.3 µmol/L Hb</td>
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<td>t CinQ HbA1c on JCA-ZS050 HbA1c%(NGSP) = 0.0915<em>HbA1c/Hb</em>1000(IFC C) + 2.15</td>
<td>Enzymatic</td>
<td>May '21</td>
<td>MFA19, MFE20</td>
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<td>2.73, 6.94 µmol/L HbA1c; 95.3 µmol/L Hb</td>
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List of NGSP Certified Methods (Updated 3/22, listed by date certified)

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<tr>
<td>Arkray, Inc.</td>
<td>t CinQ HbA1c on LABOSPECT 006 HbA1c%(NGSP) =0.0915<em>HbA1c/Hb</em>1000(IFC C)+2.15</td>
<td>Enzymatic</td>
<td>May ‘21</td>
<td>HLS30</td>
<td>2009</td>
<td>2.73, 6.94, µmol/L HbA1c; 95.3 µmol/L Hb</td>
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<td></td>
<td>t CinQ HbA1c on TBA-120FR HbA1c%(NGSP) =0.0915<em>HbA1c/Hb</em>1000(IFC C)+2.15</td>
<td>Enzymatic</td>
<td>May ‘21</td>
<td>MFA19, MFE20</td>
<td>2009</td>
<td>2.73, 6.94, µmol/L HbA1c; 95.3 µmol/L Hb</td>
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<td>Sakae Corporation</td>
<td>MEDIDAS HbA1c on A1c GEAR</td>
<td>Immuno-assay</td>
<td>May ‘21</td>
<td>462102</td>
<td>20G17</td>
<td>4.7%, 7.1%, 10.2%, 13.9%</td>
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<td>MEDIDAS HbA1c on A1c iGear</td>
<td>Immuno-assay</td>
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<td>Abbott Diagnostics</td>
<td>HbA1c (Hemolysate) on Architect c8000 %NGSP=HbA1c/Hb*91.48+2.152</td>
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<td>May ‘21</td>
<td>57337UQ06, 57337UQ06, 57337UQ06</td>
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<td>HbA1c (Hemolysate) on Architect c4000 %NGSP=HbA1c/Hb*91.48+2.152</td>
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<td>57486UQ05, 57486UQ05</td>
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<td>HbA1c (Whole Blood) on Architect c4000 %NGSP=HbA1c/Hb*91.48+2.152</td>
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<td>57850UQ08, 57850UQ08</td>
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<td>HbA1c (Whole Blood) on Architect c8000 %NGSP=HbA1c/Hb*91.48+2.152</td>
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<td>May ‘21</td>
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<td>5.2%, 11.6%</td>
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<td>HbA1c (Hemolysate) on Alinity c %NGSP=HbA1c/Hb*91.48+2.152</td>
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<td>57337UQ06, 57337UQ06, 57337UQ06</td>
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<td>HbA1c (Whole Blood) on Alinity c analyzer %NGSP=HbA1c/Hb*91.48+2.152</td>
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<td>100307, 100307, 100307, 100307</td>
<td>0KS007, 0KS007</td>
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<td>&quot;HbA1c v.2 Turbitest AA on CB 350i 91.5*HbA1c/Hb + 2.15 Immuno-assay</td>
<td>Enzymatic</td>
<td>Apr ‘21</td>
<td>416160, 416170, 416140, 413940</td>
<td>417150</td>
<td>2.708 g/dL HbA1c; 13.35 g/dL Hb</td>
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<td>Wiener Laboratorios S.A.I.C.</td>
<td>tHbA1c v2 Turbitest AA on CT600i 91.5*HbA1c/Hb + 2.15</td>
<td>Immuno-assay</td>
<td>Apr '21</td>
<td>416160, 416170, 416140, 413940</td>
<td>417150</td>
<td>2.708 g/dL HbA1c; 13.35 g/dL Hb</td>
<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>tHbA1c v2 Turbitest AA on CM 250 91.5*HbA1c/Hb + 2.15</td>
<td>Immuno-assay</td>
<td>Apr '21</td>
<td>416160, 416170, 416140, 413940</td>
<td>417150</td>
<td>2.708 g/dL HbA1c; 13.35 g/dL Hb</td>
<td>-</td>
<td>Univ. of Missouri. SRL #9</td>
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<td>tHbA1c v2 Turbitest AA on CMD 600 91.5*HbA1c/Hb + 2.15</td>
<td>Immuno-assay</td>
<td>Apr '21</td>
<td>416160, 416170, 416140, 413940</td>
<td>417150</td>
<td>2.708 g/dL HbA1c; 13.35 g/dL Hb</td>
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<td>Univ. of Missouri. SRL #9</td>
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<td>Fujirebio Inc.</td>
<td>1AU-SYNCHRON Reagent HbA1C on DxC700AU</td>
<td>Immuno-assay</td>
<td>Apr '21</td>
<td>F9A026, F9A026, H1A026</td>
<td>H2A020</td>
<td>0.0%, 4.4%, 6.9%, 9.6%, 13.2%</td>
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<td>1Rapidia Auto HbA1c-L on BiOLis24i Premium</td>
<td>Immuno-assay</td>
<td>Apr '21</td>
<td>QF00602, RF00602, SF00901</td>
<td>VF00702</td>
<td>0.0%, 4.4%, 6.9%, 9.6%, 13.2%</td>
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<td>ReCCS ASRL#1</td>
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<td>1Rapidia Auto HbA1c-L on JCA-BM9130</td>
<td>Immuno-assay</td>
<td>Apr '21</td>
<td>QF00602, RF00602, SF00901</td>
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<td>1Rapidia Auto HbA1c-L on AU680</td>
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<td>Apr '21</td>
<td>QF00602, RF00602, SF00901</td>
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<td>1Rapidia Auto HbA1c-L on Hitachi 7180</td>
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<td>Apr '21</td>
<td>QF00602, RF00602, SF00901</td>
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<td>Apr '21</td>
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<td>Abbott Diagnostics Technologies AS</td>
<td>Afinion HbA1c / Afinion AS100 Analyzer</td>
<td>Boronate affinity</td>
<td>Apr '21</td>
<td>10210303</td>
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<td>Apr '21</td>
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<td>S0003</td>
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<td>Date Certified</td>
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<td>Calibrator Lot</td>
<td>Calibrator Assigned Value</td>
<td>Column Lot</td>
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<td>Apr ’21</td>
<td>20022857, 20031158, 20091759, 20022055</td>
<td>S0003</td>
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<td>Ion-exchange HPLC</td>
<td>Apr ’21</td>
<td>200624101, 201126102, 201109105</td>
<td>S0003</td>
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<td>0J1001, 0J1023, 0L1041</td>
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<td>200624101, 201126102, 200729140, 201109105</td>
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<td>^ADAMS A1c Lite HA-8380V Fast mode</td>
<td>Ion-exchange HPLC</td>
<td>Apr ’21</td>
<td>200624101, 201126102, 200729140, 201109105</td>
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<td>^ADAMS A1c Lite HA-8380V Variant mode</td>
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<td>200624101, 201126102, 200729140, 201109105</td>
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<td>200624101, 201126102, 210205364, 201109105</td>
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<td>200624101, 201126102, 210205364, 201109105</td>
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<td>200624101, 201126102, 200916160, 201109105</td>
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<td>Ion-exchange HPLC</td>
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<td>Method/ Instrument</td>
<td>Method Type</td>
<td>Date Certified</td>
<td>Reagent Lot</td>
<td>Calibrator Lot</td>
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<td>Arkray, Inc.</td>
<td>&quot;CinQ HbA1c on JCA-BM6010&quot; HbA1c% (NGSP)=0.0915<em>HbA1c/Hb</em>1000(IFCC)+2.15</td>
<td>Enzymatic</td>
<td>Apr '21</td>
<td>MFA19, MFE20</td>
<td>CAC8F24</td>
<td>2.46, 7.39 µmol/L HbA1c (IFCC); 98.2 µmol/L Hb</td>
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<td>ReCCS ASRL#1</td>
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<td>* The Lab 001</td>
<td>&quot;HbA1c% (NGSP)=0.0915<em>HbA1c/Hb</em>1000(IFCC)+2.15&quot; Capillary Electrophoresis</td>
<td>Capillary Electrophoresis</td>
<td>Apr '21</td>
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* Method certification has been delayed due to coronavirus and/or other shipping issues.
* Method is not currently available