

Geenius HIV 1/2 Supplemental Assay IQCP QI Project Data

| Month/Year | # of control runs required per CLIA '88 | # of controls performed per CLIA '88 | # of control runs required with IQCP | # of controls required with IQCP | # of Geenius Tests Performed | Day of Use controls versus test volume (%) | Monthly controls versus test volume (%) | Direct Cost of a control run | Additional Information | Monthly Control Cost per Test, CLIA'88 | Monthly Control Cost per Test, CLIA IQCP |
|---|---|--------------------------------------|--------------------------------------|----------------------------------|------------------------------|--|---|--------------------------------------|------------------------|--|--|
| Apr-16 | 7 | 14 | 1 | 2 | 12 | 53.8% | 14.3% | \$ 92.73 | | \$ 649.11 | \$ 92.73 |
| May-16 | 9 | 18 | 1 | 2 | 17 | 51.4% | 10.5% | \$ 92.73 | | \$ 834.57 | \$ 92.73 |
| Jun-16 | 6 | 12 | 1 | 2 | 12 | 50.0% | 14.3% | \$ 92.73 | | \$ 556.38 | \$ 92.73 |
| Jul-16 | 8 | 16 | 1 | 2 | 14 | 53.3% | 12.5% | \$ 92.73 | | \$ 741.84 | \$ 92.73 |
| Aug-16 | 8 | 16 | 1 | 2 | 15 | 51.6% | 11.8% | \$ 92.73 | | \$ 741.84 | \$ 92.73 |
| Sep-16 | 6 | 12 | 1 | 2 | 9 | 57.1% | 18.2% | \$ 92.73 | New lot in use | \$ 556.38 | \$ 92.73 |
| Oct-16 | 7 | 14 | 1 | 2 | 15 | 48.3% | 11.8% | \$ 92.73 | | \$ 649.11 | \$ 92.73 |
| Nov-16 | 9 | 18 | 1 | 2 | 17 | 51.4% | 10.5% | \$ 92.73 | | \$ 834.57 | \$ 92.73 |
| Dec-16 | 7 | 14 | 1 | 2 | 15 | 48.3% | 11.8% | \$ 92.73 | | \$ 649.11 | \$ 92.73 |
| Jan-17 | 8 | 16 | 1 | 2 | 21 | 43.2% | 8.7% | \$ 92.73 | New lot in use | \$ 741.84 | \$ 92.73 |
| Feb-17 | 10 | 20 | 1 | 2 | 16 | 55.6% | 11.1% | \$ 92.73 | New lot in use | \$ 927.30 | \$ 92.73 |
| Mar-17 Estimate | 8 | 16 | 1 | 2 | 15 | 51.6% | 11.8% | \$ 92.73 | | \$ 741.84 | \$ 92.73 |
| | Totals | | | | | Averages | | Control Costs Pre IQCP and Post IQCP | | Pre-IQCP | Post-IQCP |
| Apr 16 to Feb 17 Totals (11 mos) | 85 | 170 | 11 | 22 | 163 | 51.3% | 12.3% | | | \$ 7,882.05 | \$ 1,020.03 |
| Estimated Annual Total # | 93 | 186 | 12 | 24 | 178 | 51.3% | 12.3% | | | \$ 8,623.89 | \$ 1,112.76 |

Note: All room temperatures, refrigerated temperatures, and humidity levels were within manufacturer's specifications and did not cause additional control runs. Three change of lot runs were required during the IQCP data review period.