

VitalOne™: A point-of-care platform for rapid, comprehensive, central-lab quality blood testing

| Analyte   | Units  | Vital Bio method  | Predicate method | Predicate device |      |
|-----------|--------|---|------------------|------------------|------|
| Sodium    | mmol/L | 139.00  | 139.18           | Beckman AU480    |      |
|           |        | 141.93  | 140.21           |                  |      |
|           |        | 138.82  | 138.71           |                  |      |
|           |        | 144.33  | 141.35           |                  |      |
|           |        | 140.64  | 139.93           |                  |      |
|           |        | 142.53  | 140.81           |                  |      |
|           |        | 143.84  | 141.49           |                  |      |
|           |        | 143.97  | 140.86           |                  |      |
|           |        | 142.53  | 140.81           |                  |      |
|           |        | 141.85  | 138.45           |                  |      |
|           |        | 140.72  | 143.16           |                  |      |
|           |        | 141.28  | 142.73           |                  |      |
|           |        | 140.60  | 139.39           |                  |      |
|           |        | 140.00  | 140.34           |                  |      |
|           |        | 142.81  | 142.15           |                  |      |
|           |        | 137.98  | 140.62           |                  |      |
|           |        | 137.18  | 142.44           |                  |      |
|           |        | 143.72  | 143.26           |                  |      |
|           |        | 143.72  | 143.26           |                  |      |
|           |        | 140.02  | 142.03           |                  |      |
| Potassium | mmol/L | 4.24  | 4.04             | Beckman AU480    |      |
|           |        | * -0.145 mmol/L bias<br>corrected in VitalOne<br>values | 4.48             |                  | 4.48 |
|           |        | 4.01  | 3.93             |                  |      |
|           |        | 4.18  | 3.83             |                  |      |
|           |        | 3.52  | 3.48             |                  |      |
|           |        | 4.11  | 4.07             |                  |      |
|           |        | 3.66  | 3.59             |                  |      |
|           |        | 3.92  | 4.21             |                  |      |
|           |        | 3.96  | 4.38             |                  |      |
|           |        | 3.87  | 4.15             |                  |      |
|           |        | 4.09  | 4.20             |                  |      |
|           |        | 3.52  | 3.74             |                  |      |
|           |        | 3.94  | 4.03             |                  |      |
|           |        | 6.02  | 5.89             |                  |      |
|           |        | 2.89  | 2.88             |                  |      |
|           |        | 3.02  | 2.94             |                  |      |
| Chloride  | mmol/L | 5.34  | 5.57             | Beckman AU480    |      |
|           |        | 4.90  | 4.82             |                  |      |
|           |        | 5.65  | 5.09             |                  |      |
|           |        | 5.54  | 5.54             |                  |      |
|           |        | 2.93  | 2.91             |                  |      |
|           |        | 106.84  | 103.06           |                  |      |
|           |        | 97.63   | 101.10           |                  |      |
|           |        | 104.37  | 106.05           |                  |      |
|           |        | 99.34   | 103.10           |                  |      |
|           |        | 102.65  | 105.28           |                  |      |
|           |        | 107.91  | 104.51           |                  |      |
|           |        | 93.76   | 101.64           |                  |      |
|           |        | 94.62   | 101.39           |                  |      |
|           |        | 104.04  | 104.25           |                  |      |
|           |        | 102.68  | 100.36           |                  |      |
|           |        | 105.12  | 104.36           |                  |      |
| 108.52    | 105.57 |   |                  |                  |      |
|           |        | 101.69  | 103.93           |                  |      |
|           |        | 96.85   | 85.47            |                  |      |
|           |        | 91.85   | 88.58            |                  |      |
|           |        | 103.24  | 110.89           |                  |      |
|           |        | 101.31  | 96.45            |                  |      |
|           |        | 110.73  | 105.48           |                  |      |

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|------------------|--------|------------------|------------------|------------------|
| Chloride (cont.) | mmol/L | 106.83           | 106.36           |                  |
|                  |        | 100.59           | 108.75           |                  |
|                  |        | 103.87           | 107.70           |                  |
|                  |        | 93.19            | 96.95            |                  |
|                  |        | 106.55           | 104.44           |                  |
|                  |        | 86.97            | 91.43            |                  |
|                  |        | 97.49            | 96.95            |                  |
|                  |        | Glucose          | mg/dL            |                  |
| 91.33            | 97.50  |                  |                  |                  |
| 76.34            | 74.18  |                  |                  |                  |
| 96.34            | 93.97  |                  |                  |                  |
| 71.67            | 69.32  |                  |                  |                  |
| 103.64           | 99.12  |                  |                  |                  |
| 101.65           | 101.38 |                  |                  |                  |
| 94.15            | 91.86  |                  |                  |                  |
| 97.95            | 99.63  |                  |                  |                  |
| 90.60            | 95.11  |                  |                  |                  |
| 94.15            | 94.30  |                  |                  |                  |
| 89.43            | 85.74  |                  |                  |                  |
| 88.80            | 90.04  |                  |                  |                  |
| 86.66            | 90.94  |                  |                  |                  |
| 95.61            | 92.31  |                  |                  |                  |
| 82.81            | 80.33  |                  |                  |                  |
| 85.64            | 88.36  |                  |                  |                  |
| 77.95            | 81.04  |                  |                  |                  |
| 82.08            | 84.05  |                  |                  |                  |
| 87.34            | 82.83  |                  |                  |                  |
| 206.66           | 212.09 |                  |                  |                  |
| 134.78           | 135.81 |                  |                  |                  |
| 139.31           | 143.75 |                  |                  |                  |
| 132.98           | 140.47 |                  |                  |                  |
| 188.85           | 198.79 |                  |                  |                  |
| 158.14           | 158.94 |                  |                  |                  |
| 116.88           | 120.72 |                  |                  |                  |
| 169.82           | 167.08 |                  |                  |                  |
| 200.38           | 224.49 |                  |                  |                  |
| 135.85           | 140.02 |                  |                  |                  |
| Calcium          | mg/dL  | 10.23            | 9.12             | Beckman AU480    |
|                  |        | 10.26            | 9.01             |                  |
|                  |        | 10.85            | 10.35            |                  |
|                  |        | 7.67             | 8.83             |                  |
|                  |        | 9.07             | 8.62             |                  |
|                  |        | 9.53             | 9.62             |                  |
|                  |        | 9.48             | 9.36             |                  |
|                  |        | 9.28             | 8.75             |                  |
|                  |        | 8.93             | 9.71             |                  |
|                  |        | 10.05            | 9.83             |                  |
|                  |        | 8.61             | 8.50             |                  |
|                  |        | 8.56             | 8.73             |                  |
|                  |        | 8.71             | 8.96             |                  |
|                  |        | 8.48             | 8.85             |                  |
|                  |        | 9.75             | 9.12             |                  |
|                  |        | 6.78             | 8.77             |                  |
|                  |        | 8.57             | 8.42             |                  |
|                  |        | 9.10             | 8.63             |                  |
|                  |        | 8.31             | 8.30             |                  |
|                  |        | 8.43             | 8.73             |                  |
|                  |        | 7.81             | 6.99             |                  |
|                  |        | 9.82             | 9.38             |                  |
|                  |        | 7.76             | 7.37             |                  |
|                  |        | 7.04             | 6.42             |                  |
|                  |        | 8.06             | 7.68             |                  |
| 7.63             | 7.63   |                  |                  |                  |
| 8.17             | 6.83   |                  |                  |                  |
| 7.78             | 7.12   |                  |                  |                  |

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| Analyte         | Units | Vital Bio method | Predicate method | Predicate device |
|-----------------|-------|------------------|------------------|------------------|
| Calcium (cont.) | mg/dL | 7.37             | 7.06             |                  |
|                 |       | 7.87             | 7.26             |                  |
| BUN             | mg/dL | 8.32             | 6.82             | Beckman AU480    |
|                 |       | 22.63            | 22.68            |                  |
|                 |       | 20.42            | 19.70            |                  |
|                 |       | 17.04            | 15.08            |                  |
|                 |       | 22.39            | 21.25            |                  |
|                 |       | 9.67             | 10.87            |                  |
|                 |       | 13.91            | 15.59            |                  |
|                 |       | 21.37            | 22.75            |                  |
|                 |       | 15.17            | 16.73            |                  |
|                 |       | 6.40             | 7.31             |                  |
|                 |       | 12.28            | 12.09            |                  |
|                 |       | 16.91            | 16.63            |                  |
|                 |       | 16.36            | 17.84            |                  |
|                 |       | 18.73            | 18.97            |                  |
|                 |       | 14.03            | 14.44            |                  |
|                 |       | 17.39            | 16.39            |                  |
|                 |       | 19.80            | 20.20            |                  |
|                 |       | 18.49            | 17.75            |                  |
|                 |       | 14.09            | 14.05            |                  |
|                 |       | 7.39             | 8.45             |                  |
| 33.52           | 33.70 |                  |                  |                  |
| 28.73           | 29.49 |                  |                  |                  |
| 33.60           | 36.80 |                  |                  |                  |
| 39.53           | 38.36 |                  |                  |                  |
| 27.40           | 28.29 |                  |                  |                  |
| 30.63           | 31.86 |                  |                  |                  |
| 40.02           | 40.85 |                  |                  |                  |
| 27.24           | 27.73 |                  |                  |                  |
| 27.75           | 27.12 |                  |                  |                  |
| 48.71           | 48.15 |                  |                  |                  |
| Creatinine      | mg/dL | 0.90             | 1.02             | Beckman AU480    |
|                 |       | 1.03             | 1.02             |                  |
|                 |       | 1.04             | 1.00             |                  |
|                 |       | 1.05             | 1.04             |                  |
|                 |       | 0.60             | 0.65             |                  |
|                 |       | 0.71             | 0.75             |                  |
|                 |       | 0.68             | 0.73             |                  |
|                 |       | 1.41             | 1.32             |                  |
|                 |       | 1.09             | 1.01             |                  |
|                 |       | 0.98             | 0.98             |                  |
|                 |       | 1.28             | 1.38             |                  |
|                 |       | 0.81             | 0.77             |                  |
|                 |       | 1.13             | 0.91             |                  |
|                 |       | 1.09             | 1.04             |                  |
|                 |       | 1.35             | 1.34             |                  |
|                 |       | 0.60             | 0.53             |                  |
|                 |       | 0.59             | 0.48             |                  |
|                 |       | 0.78             | 0.64             |                  |
|                 |       | 0.62             | 0.55             |                  |
|                 |       | 0.65             | 0.61             |                  |
| 0.60            | 0.44  |                  |                  |                  |
| 0.50            | 0.50  |                  |                  |                  |
| 0.73            | 0.54  |                  |                  |                  |
| 1.77            | 1.77  |                  |                  |                  |
| 2.10            | 1.84  |                  |                  |                  |
| 2.44            | 2.33  |                  |                  |                  |
| 3.79            | 3.48  |                  |                  |                  |
| 2.27            | 2.18  |                  |                  |                  |
| 1.53            | 1.61  |                  |                  |                  |
| 3.19            | 3.19  |                  |                  |                  |
| Total protein   | g/dL  | 7.01             | 6.79             | Beckman AU480    |

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| Analyte  | Units | Vital Bio method | Predicate method | Predicate device |
|--|-------|------------------|------------------|------------------|
| Total protein (cont.)                                    | g/dL  | 6.54             | 6.03             |                  |
|  |       | 7.06             | 6.98             |                  |
|  |       | 6.56             | 6.51             |                  |
|  |       | 6.07             | 6.02             |                  |
|  |       | 7.09             | 6.95             |                  |
|  |       | 6.26             | 6.06             |                  |
|  |       | 6.81             | 7.02             |                  |
|  |       | 6.93             | 6.75             |                  |
|  |       | 6.50             | 6.34             |                  |
|  |       | 6.56             | 6.48             |                  |
|  |       | 7.33             | 7.13             |                  |
|  |       | 7.06             | 6.87             |                  |
|  |       | 7.89             | 7.57             |                  |
|  |       | 7.26             | 7.11             |                  |
|  |       | 7.57             | 7.58             |                  |
|  |       | 6.61             | 6.86             |                  |
|  |       | 7.07             | 7.30             |                  |
|  |       | 7.16             | 6.78             |                  |
|  |       | 7.58             | 7.45             |                  |
|  |       | 8.72             | 8.66             |                  |
|  |       | 7.58             | 7.97             |                  |
|  |       | 7.65             | 7.98             |                  |
|  |       | 7.05             | 7.03             |                  |
|  |       | 8.96             | 8.88             |                  |
|  |       | 8.75             | 8.67             |                  |
| 8.27   | 8.30  |                  |                  |                  |
| 7.98   | 8.07  |                  |                  |                  |
| 9.69   | 9.53  |                  |                  |                  |
| 6.96   | 7.16  |                  |                  |                  |
| Albumin<br>* -2.7% bias corrected<br>in Vital Bio values | mg/dL | 3.88             | 3.90             | Beckman AU480    |
|  |       | 4.56             | 4.72             |                  |
|  |       | 4.43             | 4.27             |                  |
|  |       | 3.74             | 3.84             |                  |
|  |       | 4.97             | 4.59             |                  |
|  |       | 4.56             | 4.34             |                  |
|  |       | 4.87             | 4.54             |                  |
|  |       | 4.94             | 4.59             |                  |
|  |       | 4.28             | 4.29             |                  |
|  |       | 4.01             | 4.51             |                  |
|  |       | 4.40             | 4.51             |                  |
|  |       | 3.83             | 3.87             |                  |
|  |       | 4.18             | 4.34             |                  |
|  |       | 3.85             | 4.01             |                  |
|  |       | 4.44             | 4.48             |                  |
|  |       | 4.10             | 4.39             |                  |
|  |       | 3.88             | 3.87             |                  |
|  |       | 4.11             | 4.46             |                  |
|  |       | 4.50             | 4.78             |                  |
|  |       | 4.38             | 4.40             |                  |
|  |       | 4.99             | 5.01             |                  |
|  |       | 4.93             | 4.88             |                  |
|  |       | 4.61             | 4.84             |                  |
|  |       | 4.84             | 4.98             |                  |
|  |       | 4.91             | 4.95             |                  |
| 4.84   | 4.94  |                  |                  |                  |
| 4.82   | 4.96  |                  |                  |                  |
| 5.08   | 5.01  |                  |                  |                  |
| 4.99   | 5.21  |                  |                  |                  |
| 4.82   | 5.06  |                  |                  |                  |
| AST  | U/L   | 32.63            | 29.40            | Beckman AU480    |
|  |       | 19.76            | 20.20            |                  |
|  |       | 22.45            | 22.60            |                  |
|  |       | 30.37            | 20.10            |                  |
|  |       | 22.57            | 23.20            |                  |
|  |       | 25.52            | 22.60            |                  |

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| Analyte         | Units  | Vital Bio method | Predicate method | Predicate device |        |               |
|-----------------|--------|------------------|------------------|------------------|--------|---------------|
| AST (cont.)     | U/L    | 39.56            | 36.70            |                  |        |               |
|                 |        | 35.34            | 35.60            |                  |        |               |
|                 |        | 65.02            | 57.70            |                  |        |               |
|                 |        | 39.95            | 40.70            |                  |        |               |
|                 |        | 39.56            | 40.90            |                  |        |               |
|                 |        | 65.94            | 65.70            |                  |        |               |
|                 |        | 87.31            | 46.90            |                  |        |               |
|                 |        | 50.24            | 50.90            |                  |        |               |
|                 |        | 96.15            | 79.00            |                  |        |               |
|                 |        | 42.99            | 43.30            |                  |        |               |
|                 |        | 48.26            | 49.80            |                  |        |               |
|                 |        | ALP              | U/L              | 118.40           | 124.20 | Beckman AU480 |
|                 |        |                  |                  | 130.30           | 133.40 |               |
| 115.80          | 120.70 |                  |                  |                  |        |               |
| 33.40           | 31.40  |                  |                  |                  |        |               |
| 135.30          | 140.10 |                  |                  |                  |        |               |
| 137.10          | 134.10 |                  |                  |                  |        |               |
| 235.20          | 247.30 |                  |                  |                  |        |               |
| 114.40          | 126.80 |                  |                  |                  |        |               |
| 146.90          | 156.40 |                  |                  |                  |        |               |
| 48.50           | 49.20  |                  |                  |                  |        |               |
| 72.60           | 78.40  |                  |                  |                  |        |               |
| 73.50           | 79.50  |                  |                  |                  |        |               |
| 72.00           | 74.60  |                  |                  |                  |        |               |
| 75.90           | 75.60  |                  |                  |                  |        |               |
| 50.60           | 50.80  |                  |                  |                  |        |               |
| 70.00           | 70.80  |                  |                  |                  |        |               |
| 77.00           | 77.70  |                  |                  |                  |        |               |
| 63.80           | 73.20  |                  |                  |                  |        |               |
| 91.30           | 82.70  |                  |                  |                  |        |               |
| 71.30           | 72.00  |                  |                  |                  |        |               |
| 83.00           | 86.30  |                  |                  |                  |        |               |
| 85.80           | 85.80  |                  |                  |                  |        |               |
| 78.20           | 83.50  |                  |                  |                  |        |               |
| 45.10           | 46.50  |                  |                  |                  |        |               |
| 96.80           | 107.20 |                  |                  |                  |        |               |
| 72.10           | 77.10  |                  |                  |                  |        |               |
| 43.70           | 45.80  |                  |                  |                  |        |               |
| 109.90          | 114.00 |                  |                  |                  |        |               |
| 73.40           | 74.70  |                  |                  |                  |        |               |
| Total bilirubin | mg/dL  | 2.23             | 2.15             | Beckman AU480    |        |               |
|                 |        | 1.83             | 2.03             |                  |        |               |
|                 |        | 2.00             | 2.13             |                  |        |               |
|                 |        | 2.21             | 2.28             |                  |        |               |
|                 |        | 1.56             | 1.52             |                  |        |               |
|                 |        | 1.89             | 2.05             |                  |        |               |
|                 |        | 3.09             | 3.32             |                  |        |               |
|                 |        | 2.01             | 2.06             |                  |        |               |
|                 |        | 2.02             | 2.13             |                  |        |               |
|                 |        | 0.87             | 0.81             |                  |        |               |
|                 |        | 0.43             | 0.48             |                  |        |               |
|                 |        | 0.41             | 0.39             |                  |        |               |
|                 |        | 0.44             | 0.41             |                  |        |               |
|                 |        | 0.94             | 0.92             |                  |        |               |
|                 |        | 0.92             | 0.93             |                  |        |               |
|                 |        | 0.69             | 0.69             |                  |        |               |
|                 |        | 0.96             | 1.31             |                  |        |               |
|                 |        | 0.26             | 0.32             |                  |        |               |
|                 |        | 0.18             | 0.21             |                  |        |               |
|                 |        | 0.53             | 0.85             |                  |        |               |
|                 |        | 0.61             | 0.58             |                  |        |               |
|                 |        | 0.92             | 0.92             |                  |        |               |
|                 |        | 0.60             | 0.62             |                  |        |               |
| 0.34            | 0.23   |                  |                  |                  |        |               |
| 0.28            | 0.28   |                  |                  |                  |        |               |

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|-----------------------------------|--------|------------------|------------------|------------------|
| Total bilirubin (cont.)           | mg/dL  | 1.08             | 1.08             |                  |
|                                   |        | 0.83             | 0.92             |                  |
|                                   |        | 0.32             | 0.30             |                  |
|                                   |        |                  |                  |                  |
| Total cholesterol (whole blood)   | mg/dL  | 150.14           | 147.97           | Beckman AU480    |
|                                   |        | 170.73           | 166.06           |                  |
|                                   |        | 126.52           | 129.15           |                  |
|                                   |        | 129.48           | 129.31           |                  |
|                                   |        | 257.26           | 252.83           |                  |
|                                   |        | 118.25           | 113.83           |                  |
|                                   |        | 189.17           | 183.33           |                  |
|                                   |        | 140.07           | 140.56           |                  |
|                                   |        | 157.20           | 157.92           |                  |
|                                   |        | 200.13           | 199.30           |                  |
|                                   |        | 192.46           | 199.62           |                  |
|                                   |        | 156.13           | 166.62           |                  |
|                                   |        | 196.57           | 200.93           |                  |
|                                   |        | 213.32           | 204.10           |                  |
|                                   |        | 167.23           | 164.35           |                  |
|                                   |        | 140.12           | 137.71           |                  |
| 127.67                            | 127.03 |                  |                  |                  |
| 159.09                            | 164.35 |                  |                  |                  |
| Total cholesterol (Li-Hep plasma) | mg/dL  | 151.08           | 147.97           | Beckman AU480    |
|                                   |        | 165.35           | 166.06           |                  |
|                                   |        | 130.76           | 129.15           |                  |
|                                   |        | 129.15           | 129.31           |                  |
|                                   |        | 262.11           | 252.83           |                  |
|                                   |        | 115.96           | 113.83           |                  |
|                                   |        | 189.50           | 183.33           |                  |
|                                   |        | 142.41           | 140.56           |                  |
|                                   |        | 159.51           | 157.92           |                  |
|                                   |        | 201.28           | 199.30           |                  |
|                                   |        | 209.96           | 199.62           |                  |
|                                   |        | 159.29           | 166.62           |                  |
|                                   |        | 193.34           | 200.93           |                  |
|                                   |        | 193.20           | 204.10           |                  |
|                                   |        | 169.72           | 164.35           |                  |
|                                   |        | 145.09           | 137.71           |                  |
| 132.78                            | 127.03 |                  |                  |                  |
| 167.50                            | 164.35 |                  |                  |                  |
| Triglycerides                     | mg/dL  | 55.30            | 57.54            | Beckman AU480    |
|                                   |        | 50.21            | 59.89            |                  |
|                                   |        | 59.54            | 58.33            |                  |
|                                   |        | 69.20            | 79.50            |                  |
|                                   |        | 42.41            | 42.66            |                  |
|                                   |        | 129.40           | 137.97           |                  |
|                                   |        | 48.35            | 60.59            |                  |
|                                   |        | 145.34           | 141.20           |                  |
|                                   |        | 55.64            | 65.38            |                  |
|                                   |        | 124.99           | 139.96           |                  |
|                                   |        | 35.97            | 50.80            |                  |
|                                   |        | 55.35            | 59.89            |                  |
|                                   |        | 81.71            | 85.75            |                  |
|                                   |        | 76.32            | 106.57           |                  |
|                                   |        | 61.91            | 67.33            |                  |
|                                   |        | 308.97           | 352.84           |                  |
| 235.55                            | 250.32 |                  |                  |                  |
| 198.58                            | 231.73 |                  |                  |                  |
| 220.12                            | 248.70 |                  |                  |                  |
| 252.16                            | 247.86 |                  |                  |                  |
| 216.05                            | 243.34 |                  |                  |                  |
| 164.00                            | 135.94 |                  |                  |                  |
| 75.00                             | 74.59  |                  |                  |                  |
| Triglycerides                     | mg/dL  | 359.00           | 316.66           |                  |

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| Analyte                                       | Units | Vital Bio method | Predicate method | Predicate device  |
|---|-------|------------------|------------------|-------------------|
| Triglycerides (cont.)                         | mg/dL | 219.00           | 192.66           |                   |
|   |       | 69.00            | 75.75            |                   |
|   |       | 112.00           | 99.94            |                   |
|   |       | 152.00           | 149.03           |                   |
|   |       | 102.00           | 102.03           |                   |
|   |       | 219.00           | 215.15           |                   |
|   |       | 119.00           | 130.21           |                   |
|   |       | 156.00           | 150.05           |                   |
|   |       | 256.00           | 250.71           |                   |
|   |       | GGT              | U/L              | 199.80            |
| * -3.6% bias corrected<br>in Vital Bio values |       | 75.39            | 79.20            |                   |
|   |       | 90.45            | 94.10            |                   |
|   |       | 157.44           | 160.30           |                   |
|   |       | 238.07           | 251.30           |                   |
|   |       | 335.11           | 359.60           |                   |
|   |       | 277.68           | 294.10           |                   |
|   |       | 82.64            | 81.40            |                   |
|   |       | 209.96           | 208.90           |                   |
|   |       | 15.42            | 12.10            |                   |
|   |       | 14.84            | 13.10            |                   |
|   |       | 21.34            | 19.70            |                   |
|   |       | 28.20            | 29.50            |                   |
|   |       | 21.43            | 21.60            |                   |
|   |       | 11.76            | 12.20            |                   |
|   |       | 38.24            | 40.00            |                   |
|   |       | 42.66            | 43.60            |                   |
|   |       | 30.41            | 28.90            |                   |
|   |       | 10.96            | 11.40            |                   |
|   |       | 19.66            | 19.80            |                   |
|   |       | 15.05            | 17.70            |                   |
|   |       | 19.21            | 20.30            |                   |
|   |       | 14.99            | 15.00            |                   |
|   |       | 62.04            | 62.40            |                   |
|   |       | 29.59            | 24.80            |                   |
|   |       | 27.97            | 26.40            |                   |
|   |       | 5.18             | 6.00             |                   |
|   |       | 22.79            | 21.60            |                   |
|   |       | 8.29             | 8.50             |                   |
| TSH   | mIU/L | 0.67             | 0.67             | Beckman Access II |
|   |       | 5.30             | 5.45             |                   |
|   |       | 28.61            | 29.33            |                   |
|   |       | 1.26             | 1.09             |                   |
|   |       | 0.64             | 0.70             |                   |
|   |       | 6.82             | 8.17             |                   |
|   |       | 1.54             | 1.44             |                   |
|   |       | 1.01             | 1.36             |                   |
|   |       | 2.07             | 0.72             |                   |
|   |       | 2.22             | 2.05             |                   |
|   |       | 0.59             | 0.73             |                   |
|   |       | 1.34             | 1.52             |                   |
|   |       | 0.62             | 0.70             |                   |
|   |       | 1.64             | 1.87             |                   |
|   |       | 1.39             | 1.58             |                   |
|   |       | 0.94             | 1.08             |                   |
| 2.27  | 2.66  |                  |                  |                   |
| 0.65  | 0.70  |                  |                  |                   |
| 8.19  | 8.13  |                  |                  |                   |
| Free T4                                       | ng/dL | 0.60             | 0.81             | Beckman Access II |
|   |       | 2.64             | 2.56             |                   |
|   |       | 3.20             | 3.35             |                   |
|   |       | 0.48             | 0.57             |                   |
|   |       | 0.62             | 0.64             |                   |
|   |       | 0.82             | 0.66             |                   |
|   |       | 1.09             | 0.57             |                   |

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| Analyte  | Units     | Vital Bio method  | Predicate method | Predicate device |      |      |                 |
|--|-----------|---|------------------|------------------|------|------|-----------------|
| Free T4 (cont.)  | ng/dL     | 0.62  | 0.67             |                  |      |      |                 |
|  |           | 0.89  | 0.90             |                  |      |      |                 |
|  |           | 0.66  | 0.57             |                  |      |      |                 |
|  |           | 0.73  | 0.64             |                  |      |      |                 |
|  |           | 1.03  | 0.57             |                  |      |      |                 |
|  |           | 0.57  | 0.67             |                  |      |      |                 |
|  |           | 0.82  | 0.65             |                  |      |      |                 |
|  |           | 1.08  | 0.84             |                  |      |      |                 |
|  |           | 0.96  | 0.84             |                  |      |      |                 |
|  |           | 1.10  | 0.69             |                  |      |      |                 |
|  |           | 1.34  | 0.93             |                  |      |      |                 |
|  |           | 1.59  | 1.23             |                  |      |      |                 |
|  |           | 0.70  | 0.94             |                  |      |      |                 |
|  |           | 0.91  | 0.71             |                  |      |      |                 |
|  |           | 0.82  | 0.76             |                  |      |      |                 |
|  |           | 0.83  | 0.83             |                  |      |      |                 |
|  |           | 0.80  | 0.82             |                  |      |      |                 |
|  |           | 1.34  | 1.28             |                  |      |      |                 |
|  |           | 0.81  | 0.80             |                  |      |      |                 |
|  |           | 0.57  | 0.91             |                  |      |      |                 |
| 0.81   | 1.15      |   |                  |                  |      |      |                 |
| D-dimer  | ng/mL FEU | 230.08  | 303.00           | Sysmex 140       |      |      |                 |
|  |           | 499.59  | 599.00           |                  |      |      |                 |
|  |           | 2114.74   | 2083.00          |                  |      |      |                 |
|  |           | 451.82  | 599.00           |                  |      |      |                 |
|  |           | 572.13  | 484.00           |                  |      |      |                 |
|  |           | 120.28  | 190.00           |                  |      |      |                 |
|  |           | 149.89  | 190.00           |                  |      |      |                 |
|  |           | 188.77  | 190.00           |                  |      |      |                 |
|  |           | 356.12  | 309.00           |                  |      |      |                 |
|  |           | 377.32  | 190.00           |                  |      |      |                 |
|  |           | 363.83  | 428.00           |                  |      |      |                 |
|  |           | 252.33  | 195.00           |                  |      |      |                 |
|  |           | 400.48  | 417.00           |                  |      |      |                 |
|  |           | 211.19  | 190.00           |                  |      |      |                 |
|  |           | 218.11  | 190.00           |                  |      |      |                 |
|  |           | 196.81  | 190.00           |                  |      |      |                 |
|  |           | 184.65  | 195.00           |                  |      |      |                 |
|  |           | 355.52  | 190.00           |                  |      |      |                 |
|  |           | 274.27  | 190.00           |                  |      |      |                 |
|  |           | 250.83  | 190.00           |                  |      |      |                 |
| hsCRP<br>* +7.8% bias corrected<br>in Vital Bio values | mg/L      | 0.72  | 0.64             | Beckman AU480    |      |      |                 |
|  |           | 2.11  | 2.12             |                  |      |      |                 |
|  |           | 5.40  | 5.69             |                  |      |      |                 |
|  |           | 0.49  | 0.47             |                  |      |      |                 |
|  |           | 0.78  | 0.99             |                  |      |      |                 |
|  |           | 0.16  | 0.15             |                  |      |      |                 |
|  |           | 0.60  | 0.52             |                  |      |      |                 |
|  |           | 1.77  | 1.53             |                  |      |      |                 |
|  |           | 0.13  | 0.14             |                  |      |      |                 |
|  |           | 0.65  | 0.52             |                  |      |      |                 |
|  |           | 2.21  | 1.68             |                  |      |      |                 |
|  |           | 2.75  | 2.27             |                  |      |      |                 |
|  |           | 0.34  | 0.51             |                  |      |      |                 |
|  |           | 0.47  | 0.38             |                  |      |      |                 |
|  |           | 0.82  | 0.67             |                  |      |      |                 |
|  |           | 0.29  | 0.34             |                  |      |      |                 |
|  |           | 0.54  | 0.55             |                  |      |      |                 |
|  |           | 0.40  | 0.50             |                  |      |      |                 |
|  |           | RBC count<br>* +14.26% bias<br>corrected in Vital Bio<br>values | M/ $\mu$ L       |                  | 4.30 | 4.52 | Beckman DxH 500 |
|  |           |   |                  |                  | 4.74 | 4.88 |                 |
| 4.60   | 4.70      |   |                  |                  |      |      |                 |
| 4.60   | 4.68      |   |                  |                  |      |      |                 |
| 5.39   | 5.32      |   |                  |                  |      |      |                 |



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| Analyte           | Units      | Vital Bio method   | Predicate method | Predicate device |      |                 |
|-------------------|------------|--|------------------|------------------|------|-----------------|
| RBC count (cont.) | M/ $\mu$ L | 4.98   | 4.80             |                  |      |                 |
|                   |            | 5.02   | 4.92             |                  |      |                 |
|                   |            | 4.63   | 4.50             |                  |      |                 |
|                   |            | 3.74   | 4.04             |                  |      |                 |
|                   |            | 5.26   | 5.26             |                  |      |                 |
|                   |            | 3.85   | 3.87             |                  |      |                 |
|                   |            | 4.75   | 4.92             |                  |      |                 |
|                   |            | 5.63   | 5.38             |                  |      |                 |
|                   |            | 5.05   | 5.08             |                  |      |                 |
|                   |            | 3.92   | 4.04             |                  |      |                 |
|                   |            | 5.19   | 5.37             |                  |      |                 |
|                   |            | 3.84   | 3.85             |                  |      |                 |
|                   |            | 4.34   | 4.62             |                  |      |                 |
|                   |            | 3.94   | 4.13             |                  |      |                 |
|                   |            | 3.72   | 3.83             |                  |      |                 |
|                   |            | 4.74   | 4.66             |                  |      |                 |
|                   |            | 3.40   | 3.61             |                  |      |                 |
|                   |            | 5.52   | 5.98             |                  |      |                 |
|                   |            | WBC count<br>* -11.42% bias corrected<br>in Vital Bio values | K/ $\mu$ L       | 6.38             | 6.13 | Beckman DxH 500 |
|                   |            |  |                  | 4.22             | 3.91 |                 |
| 8.42              | 8.82       |  |                  |                  |      |                 |
| 6.43              | 6.35       |  |                  |                  |      |                 |
| 3.52              | 3.58       |  |                  |                  |      |                 |
| 8.04              | 7.81       |  |                  |                  |      |                 |
| 6.87              | 6.65       |  |                  |                  |      |                 |
| 6.17              | 6.34       |  |                  |                  |      |                 |
| 9.29              | 9.01       |  |                  |                  |      |                 |
| 4.23              | 4.27       |  |                  |                  |      |                 |
| 6.60              | 6.60       |  |                  |                  |      |                 |
| 4.43              | 4.33       |  |                  |                  |      |                 |
| 6.41              | 6.69       |  |                  |                  |      |                 |
| 4.33              | 4.65       |  |                  |                  |      |                 |
| 6.20              | 6.04       |  |                  |                  |      |                 |
| 6.48              | 6.34       |  |                  |                  |      |                 |
| 7.64              | 7.79       |  |                  |                  |      |                 |
| 6.55              | 6.51       |  |                  |                  |      |                 |
| 7.80              | 8.02       |  |                  |                  |      |                 |
| 7.52              | 7.44       |  |                  |                  |      |                 |
| 8.03              | 7.39       |  |                  |                  |      |                 |
| 6.53              | 6.74       |  |                  |                  |      |                 |
| 9.18              | 9.19       |  |                  |                  |      |                 |
| 6.50              | 6.74       |  |                  |                  |      |                 |
| 6.40              | 6.79       |  |                  |                  |      |                 |
| 6.18              | 6.54       |  |                  |                  |      |                 |
| 3.86              | 3.98       |  |                  |                  |      |                 |
| 6.37              | 6.76       |  |                  |                  |      |                 |
| 6.44              | 6.82       |  |                  |                  |      |                 |
| 6.19              | 6.31       |  |                  |                  |      |                 |
| 6.89              | 7.06       |  |                  |                  |      |                 |
| 8.50              | 8.15       |  |                  |                  |      |                 |
| Hemoglobin        | g/dL       | 14.71  | 15.20            | Beckman DxH 500  |      |                 |
|                   |            | 14.78  | 14.73            |                  |      |                 |
|                   |            | 17.04  | 16.09            |                  |      |                 |
|                   |            | 17.19  | 16.80            |                  |      |                 |
|                   |            | 11.91  | 12.05            |                  |      |                 |
|                   |            | 13.28  | 13.14            |                  |      |                 |
|                   |            | 13.24  | 13.03            |                  |      |                 |
|                   |            | 13.14  | 13.33            |                  |      |                 |
|                   |            | 13.73  | 13.56            |                  |      |                 |
|                   |            | 15.19  | 14.98            |                  |      |                 |
|                   |            | 14.45  | 14.73            |                  |      |                 |
|                   |            | 12.99  | 12.83            |                  |      |                 |
|                   |            | 13.59  | 13.32            |                  |      |                 |
|                   |            | 16.01  | 15.62            |                  |      |                 |
|                   |            | 15.52  | 15.46            |                  |      |                 |

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| Analyte  | Units      | Vital Bio method | Predicate method | Predicate device       |
|--|------------|------------------|------------------|------------------------|
| Hemoglobin (cont.)   | g/dL       |                  | 14.39            | 14.23                  |
|  |            |                  | 13.47            | 13.56                  |
|  |            |                  | 13.00            | 13.17                  |
|  |            |                  | 13.66            | 13.63                  |
|  |            |                  | 15.01            | 15.12                  |
|  |            |                  | 13.01            | 13.35                  |
|  |            |                  | 15.28            | 15.02                  |
|  |            |                  | 14.75            | 15.02                  |
|  |            |                  | 14.91            | 15.10                  |
|  |            |                  | 16.22            | 16.37                  |
|  |            |                  | 14.05            | 14.08                  |
|  |            |                  | 12.95            | 12.93                  |
|  |            |                  | 14.47            | 14.99                  |
|  |            |                  | 14.63            | 14.38                  |
|  |            |                  | 13.81            | 13.56                  |
|  |            |                  | 16.12            | 16.33                  |
|  |            |                  | 13.34            | 13.74                  |
|  |            |                  | 12.48            | 12.73                  |
|  | 15.00      | 14.75            |                  |                        |
| MCV  | fL         |                  | 95.26            | 94.10 Beckman DxH 500  |
|  |            |                  | 91.61            | 91.70                  |
|  |            |                  | 92.96            | 92.20                  |
|  |            |                  | 90.81            | 89.40                  |
|  |            |                  | 85.70            | 84.40                  |
|  |            |                  | 87.80            | 86.20                  |
|  |            |                  | 87.54            | 86.60                  |
|  |            |                  | 95.19            | 94.00                  |
|  |            |                  | 94.08            | 92.60                  |
|  |            |                  | 86.06            | 85.60                  |
|  |            |                  | 80.14            | 82.50                  |
|  |            |                  | 87.49            | 87.60                  |
|  |            |                  | 81.11            | 80.70                  |
|  |            |                  | 87.44            | 86.60                  |
|  |            |                  | 90.58            | 89.79                  |
|  |            |                  | 87.86            | 87.05                  |
|  |            |                  | 95.76            | 94.78                  |
|  |            |                  | 95.00            | 94.05                  |
|  | 91.16      | 90.38            |                  |                        |
|  | 97.64      | 96.28            |                  |                        |
|  | 84.81      | 84.58            |                  |                        |
|  | 90.88      | 89.75            |                  |                        |
|  | 87.55      | 87.65            |                  |                        |
| Platelet count<br>* -13.63% bias<br>corrected in Vital Bio<br>values | K/ $\mu$ L |                  | 244.52           | 251.60 Beckman DxH 500 |
|  |            |                  | 257.05           | 237.40                 |
|  |            |                  | 180.16           | 178.80                 |
|  |            |                  | 256.41           | 264.40                 |
|  |            |                  | 258.75           | 270.20                 |
|  |            |                  | 228.46           | 233.10                 |
|  |            |                  | 188.77           | 192.10                 |
|  |            |                  | 235.77           | 247.20                 |
|  |            |                  | 331.99           | 275.77                 |
|  |            |                  | 186.04           | 214.40                 |
|  |            |                  | 215.02           | 224.93                 |
|  |            |                  | 164.82           | 164.75                 |
|  |            |                  | 212.93           | 216.40                 |
|  |            |                  | 347.53           | 339.85                 |
|  |            |                  | 248.96           | 254.15                 |
|  | 171.51     | 167.70           |                  |                        |
| RDW  | %          |                  | 12.59            | 13.00 Beckman DxH 500  |
|  |            |                  | 13.10            | 12.50                  |
|  |            |                  | 13.67            | 13.40                  |
|  |            |                  | 12.83            | 12.70                  |
|  |            |                  | 13.32            | 13.70                  |

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| Analyte     | Units | Vital Bio method | Predicate method | Predicate device |       |                 |
|-------------|-------|------------------|------------------|------------------|-------|-----------------|
| RDW (cont.) | %     | 17.21            | 16.70            |                  |       |                 |
|             |       | 13.76            | 13.90            |                  |       |                 |
|             |       | 13.65            | 13.50            |                  |       |                 |
|             |       | 12.88            | 12.70            |                  |       |                 |
|             |       | 13.35            | 13.90            |                  |       |                 |
|             |       | 17.82            | 16.20            |                  |       |                 |
|             |       | 14.59            | 14.30            |                  |       |                 |
|             |       | 13.59            | 14.53            |                  |       |                 |
|             |       | 13.27            | 13.40            |                  |       |                 |
|             |       | 12.94            | 12.63            |                  |       |                 |
|             |       | 13.35            | 13.33            |                  |       |                 |
|             |       | 13.16            | 12.73            |                  |       |                 |
|             |       | 12.55            | 12.88            |                  |       |                 |
|             |       | 14.77            | 14.25            |                  |       |                 |
|             |       | 14.04            | 13.00            |                  |       |                 |
|             |       | 13.32            | 13.80            |                  |       |                 |
|             |       | 13.59            | 12.90            |                  |       |                 |
|             |       | 13.13            | 13.10            |                  |       |                 |
|             |       | Lymphocyte %     | %                | 29.97            | 28.48 | Beckman DxH 500 |
|             |       |                  |                  | 33.15            | 34.23 |                 |
| 15.50       | 16.60 |                  |                  |                  |       |                 |
| 28.74       | 29.41 |                  |                  |                  |       |                 |
| 43.64       | 41.29 |                  |                  |                  |       |                 |
| 16.77       | 17.71 |                  |                  |                  |       |                 |
| 40.65       | 38.87 |                  |                  |                  |       |                 |
| 41.00       | 40.74 |                  |                  |                  |       |                 |
| 24.23       | 23.67 |                  |                  |                  |       |                 |
| 34.56       | 36.72 |                  |                  |                  |       |                 |
| 33.09       | 32.11 |                  |                  |                  |       |                 |
| 29.40       | 28.97 |                  |                  |                  |       |                 |
| 36.20       | 36.58 |                  |                  |                  |       |                 |
| 27.57       | 31.30 |                  |                  |                  |       |                 |
| 36.67       | 37.96 |                  |                  |                  |       |                 |
| 27.06       | 28.91 |                  |                  |                  |       |                 |
| 34.22       | 36.84 |                  |                  |                  |       |                 |
| 35.85       | 36.12 |                  |                  |                  |       |                 |
| 20.20       | 21.02 |                  |                  |                  |       |                 |
| 31.87       | 32.36 |                  |                  |                  |       |                 |
| 25.15       | 23.60 |                  |                  |                  |       |                 |
| 27.19       | 26.49 |                  |                  |                  |       |                 |
| 17.41       | 19.09 |                  |                  |                  |       |                 |
| 28.36       | 29.75 |                  |                  |                  |       |                 |
| 27.89       | 27.22 |                  |                  |                  |       |                 |
| 31.74       | 32.67 |                  |                  |                  |       |                 |
| 35.61       | 39.43 |                  |                  |                  |       |                 |
| 35.83       | 36.37 |                  |                  |                  |       |                 |
| 35.53       | 37.70 |                  |                  |                  |       |                 |
| 23.89       | 24.33 |                  |                  |                  |       |                 |
| 28.84       | 30.00 |                  |                  |                  |       |                 |
| 26.69       | 24.66 |                  |                  |                  |       |                 |
| Mid %       | %     | 11.17            | 12.61            | Beckman DxH 500  |       |                 |
|             |       | 10.95            | 11.57            |                  |       |                 |
|             |       | 10.33            | 9.10             |                  |       |                 |
|             |       | 13.46            | 15.29            |                  |       |                 |
|             |       | 12.79            | 13.47            |                  |       |                 |
|             |       | 9.43             | 8.33             |                  |       |                 |
|             |       | 12.59            | 11.57            |                  |       |                 |
|             |       | 14.37            | 13.23            |                  |       |                 |
|             |       | 7.37             | 7.95             |                  |       |                 |
|             |       | 13.95            | 13.43            |                  |       |                 |
|             |       | 7.73             | 6.67             |                  |       |                 |
|             |       | 12.72            | 11.53            |                  |       |                 |
|             |       | 14.73            | 14.78            |                  |       |                 |
|             |       | 18.58            | 18.45            |                  |       |                 |
| 8.23        | 7.55  |                  |                  |                  |       |                 |

VitalOne™: A point-of-care platform for rapid, comprehensive, central-lab quality blood testing

| Analyte       | Units | Vital Bio method | Predicate method | Predicate device |       |                 |
|---------------|-------|------------------|------------------|------------------|-------|-----------------|
| Mid % (cont.) | %     | 12.15            | 12.15            |                  |       |                 |
|               |       | 16.77            | 17.62            |                  |       |                 |
|               |       | 9.75             | 10.29            |                  |       |                 |
|               |       | 10.70            | 9.06             |                  |       |                 |
|               |       | 8.52             | 9.67             |                  |       |                 |
|               |       | 8.07             | 8.45             |                  |       |                 |
|               |       | 8.34             | 8.11             |                  |       |                 |
|               |       | 13.60            | 12.16            |                  |       |                 |
|               |       | 10.89            | 9.01             |                  |       |                 |
|               |       | 6.46             | 6.82             |                  |       |                 |
|               |       | 10.18            | 11.67            |                  |       |                 |
|               |       | 15.41            | 11.48            |                  |       |                 |
|               |       | 12.19            | 12.34            |                  |       |                 |
|               |       | 12.09            | 13.92            |                  |       |                 |
|               |       | 12.25            | 12.14            |                  |       |                 |
|               |       | 10.74            | 11.09            |                  |       |                 |
|               |       | 13.42            | 14.18            |                  |       |                 |
|               |       | Granulocyte %    | %                | 58.86            | 58.92 | Beckman DxH 500 |
|               |       |                  |                  | 55.90            | 54.20 |                 |
| 74.17         | 74.31 |                  |                  |                  |       |                 |
| 57.80         | 55.31 |                  |                  |                  |       |                 |
| 43.57         | 45.24 |                  |                  |                  |       |                 |
| 73.80         | 73.97 |                  |                  |                  |       |                 |
| 46.75         | 49.55 |                  |                  |                  |       |                 |
| 44.63         | 46.03 |                  |                  |                  |       |                 |
| 68.40         | 68.39 |                  |                  |                  |       |                 |
| 51.49         | 49.85 |                  |                  |                  |       |                 |
| 59.19         | 61.22 |                  |                  |                  |       |                 |
| 57.88         | 59.50 |                  |                  |                  |       |                 |
| 49.08         | 48.64 |                  |                  |                  |       |                 |
| 53.85         | 50.25 |                  |                  |                  |       |                 |
| 55.10         | 54.49 |                  |                  |                  |       |                 |
| 60.79         | 58.95 |                  |                  |                  |       |                 |
| 49.01         | 45.53 |                  |                  |                  |       |                 |
| 54.40         | 53.59 |                  |                  |                  |       |                 |
| 69.11         | 69.92 |                  |                  |                  |       |                 |
| 59.61         | 57.98 |                  |                  |                  |       |                 |
| 66.79         | 67.94 |                  |                  |                  |       |                 |
| 64.47         | 65.40 |                  |                  |                  |       |                 |
| 68.99         | 68.76 |                  |                  |                  |       |                 |
| 60.75         | 61.24 |                  |                  |                  |       |                 |
| 65.65         | 65.96 |                  |                  |                  |       |                 |
| 58.08         | 55.66 |                  |                  |                  |       |                 |
| 48.97         | 49.08 |                  |                  |                  |       |                 |
| 51.98         | 51.29 |                  |                  |                  |       |                 |
| 52.38         | 48.39 |                  |                  |                  |       |                 |
| 63.85         | 63.54 |                  |                  |                  |       |                 |
| 60.42         | 58.91 |                  |                  |                  |       |                 |
| 59.89         | 61.15 |                  |                  |                  |       |                 |
| Hematocrit    | %     | 40.92            | 42.50            | Beckman DxH 500  |       |                 |
|               |       | 43.44            | 44.70            |                  |       |                 |
|               |       | 42.80            | 44.30            |                  |       |                 |
|               |       | 41.73            | 41.80            |                  |       |                 |
|               |       | 46.22            | 44.90            |                  |       |                 |
|               |       | 43.74            | 41.40            |                  |       |                 |
|               |       | 43.98            | 42.60            |                  |       |                 |
|               |       | 44.07            | 42.30            |                  |       |                 |
|               |       | 35.17            | 37.40            |                  |       |                 |
|               |       | 45.23            | 45.00            |                  |       |                 |
|               |       | 30.85            | 31.90            |                  |       |                 |
|               |       | 41.56            | 43.10            |                  |       |                 |
|               |       | 45.69            | 43.40            |                  |       |                 |
|               |       | 44.16            | 44.00            |                  |       |                 |
|               |       | 35.49            | 37.00            |                  |       |                 |
| 45.58         | 46.73 |                  |                  |                  |       |                 |

VitalOne™: A point-of-care platform for rapid, comprehensive, central-lab quality blood testing

| Analyte            | Units | Vital Bio method | Predicate method | Predicate device |
|--------------------|-------|------------------|------------------|------------------|
| Hematocrit (cont.) | %     |                  | 36.78            | 36.50            |
|                    |       |                  | 41.21            | 43.48            |
|                    |       |                  | 35.88            | 37.33            |
|                    |       |                  | 36.33            | 36.90            |
|                    |       |                  | 40.21            | 39.43            |
|                    |       |                  | 30.93            | 32.38            |
|                    |       |                  | 48.34            | 52.43            |