**RUMAH SAKIT ANGKATAN UDARA dr. M. SALAMUN**
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# EVALUATION OF
# DiVi LAB OPTIMA 4 IN 1 GCU-BP METER DEVICE FOR INSPECTION DiVi LAB GLUCOSE TEST STRIP IN RSAU dr M SALAMUN

A. AIM

This evaluation was done in RSAU dr. M. Salamun Pathology Laboratory, on July 2025, The aim of this evaluation is to assess the performance of reagent DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Glucose Test Strip.

B. EVALUATION SAMPLE

Sample was analyzed using Dialab Autolyser in RSAU dr. M. Salamun Pathology Laboratory, 150 samples collected from patient in RSAU dr. M. Salamun who are checked for DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Glucose Test Strip tested and being with chemistry autolyzer using samples.

C. RESULT

Sample was tested using reagent DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Glucose Test Strip, with result :

**CLINICAL TEST POCT DiVi LAB OPTIMA 4 IN 1 GCU-BP METER**

**PARAMETER : GLUCOSE (DiVi Lab Glucose Test Strip)**

LOT STRIP : 20250603

| NO | NAME | RSAU dr M SALAMUN | DiVi LAB OPTIMA 4 IN 1 GCU-BP METER DEVICE AND DiVi LAB GLUCOSE TEST STRIP | CV % | CCV % |
|---|---|---|---|---|---|
| 1 | A | 127 | 114 | 7.63 | 7,7 |
| 2 | C | 76 | 76 | 0.00 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 3 | D | 72 | 73 | 0.98 | 7,7 |
| 4 | E | 83 | 75 | 7.16 | 7,7 |
| 5 | F | 87 | 80 | 5.93 | 7,7 |
| 6 | G | 86 | 87 | 0.82 | 7,7 |
| 7 | S | 77 | 76 | 0.92 | 7,7 |
| 8 | R | 90 | 88 | 1.59 | 7,7 |
| 9 | | 90 | 91 | 0.78 | 7,7 |
| 10 | D | 141 | 151 | 4.84 | 7,7 |
| 11 | | 141 | 149 | 3.90 | 7,7 |
| 12 | K | 121 | 127 | 3.42 | 7,7 |
| 13 | | 122 | 128 | 3.39 | 7,7 |
| 14 | DJ | 133 | 145 | 6.10 | 7,7 |
| 15 | | 133 | 143 | 5.12 | 7,7 |
| 16 | S | 163 | 176 | 5.42 | 7,7 |
| 17 | | 163 | 168 | 2.14 | 7,7 |
| 18 | | 164 | 169 | 2.12 | 7,7 |
| 19 | A | 315 | 343 | 6.02 | 7,7 |
| 20 | | 316 | 344 | 6.00 | 7,7 |
| 21 | | 317 | 345 | 5.98 | 7,7 |
| 22 | D | 131 | 137 | 3.17 | 7,7 |
| 23 | | 132 | 138 | 3.14 | 7,7 |
| 24 | | 131 | 134 | 1.60 | 7,7 |
| 25 | N | 118 | 129 | 6.30 | 7,7 |
| 26 | | 118 | 124 | 3.51 | 7,7 |
| 27 | | 119 | 125 | 3.48 | 7,7 |
| 28 | A | 119 | 120 | 0.59 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 29 | | 119 | 123 | 2.34 | 7,7 |
| 30 | A | 78 | 84 | 5.24 | 7,7 |
| 31 | | 78 | 83 | 4.39 | 7,7 |
| 32 | W | 112 | 115 | 1.87 | 7,7 |
| 33 | | 112 | 113 | 0.63 | 7,7 |
| 34 | N | 168 | 175 | 2.89 | 7,7 |
| 35 | | 168 | 180 | 4.88 | 7,7 |
| 36 | A | 274 | 285 | 2.78 | 7,7 |
| 37 | | 274 | 289 | 3.77 | 7,7 |
| 38 | R | 98 | 106 | 5.55 | 7,7 |
| 39 | | 98 | 103 | 3.52 | 7,7 |
| 40 | D | 147 | 145 | 0.97 | 7,7 |
| 41 | | 147 | 146 | 0.48 | 7,7 |
| 42 | J | 240 | 247 | 2.03 | 7,7 |
| 43 | | 240 | 249 | 2.60 | 7,7 |
| 44 | L | 109 | 113 | 2.55 | 7,7 |
| 45 | | 109 | 101 | 5.39 | 7,7 |
| 46 | M | 80 | 85 | 4.29 | 7,7 |
| 47 | | 80 | 87 | 5.93 | 7,7 |
| 48 | W | 85 | 89 | 3.25 | 7,7 |
| 49 | | 85 | 88 | 2.45 | 7,7 |
| 50 | A | 70 | 69 | 1.02 | 7,7 |
| 51 | | 70 | 67 | 3.10 | 7,7 |
| 52 | D | 82 | 82 | 0.00 | 7,7 |
| 53 | | 82 | 80 | 1.75 | 7,7 |
| 54 | T | 68 | 66 | 2.11 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 55 | | 68 | 67 | 1.05 | 7,7 |
| 56 | F | 81 | 79 | 1.77 | 7,7 |
| 57 | | 81 | 80 | 0.88 | 7,7 |
| 58 | M | 92 | 98 | 4.47 | 7,7 |
| 59 | | 92 | 98 | 4.47 | 7,7 |
| 60 | M | 190 | 198 | 2.92 | 7,7 |
| 61 | | 190 | 208 | 6.40 | 7,7 |
| 62 | N | 110 | 111 | 0.64 | 7,7 |
| 63 | | 110 | 108 | 1.30 | 7,7 |
| 64 | T | 98 | 99 | 0.72 | 7,7 |
| 65 | | 98 | 101 | 2.13 | 7,7 |
| 66 | A | 99 | 109 | 6.80 | 7,7 |
| 67 | | 99 | 107 | 5.49 | 7,7 |
| 68 | W | 104 | 105 | 0.68 | 7,7 |
| 69 | | 104 | 108 | 2.67 | 7,7 |
| 70 | | 104 | 101 | 2.07 | 7,7 |
| 71 | M | 128 | 133 | 2.71 | 7,7 |
| 72 | | 128 | 134 | 3.24 | 7,7 |
| 73 | | 128 | 130 | 1.10 | 7,7 |
| 74 | S | 115 | 116 | 0.61 | 7,7 |
| 75 | | 115 | 112 | 1.87 | 7,7 |
| 76 | | 115 | 112 | 1.87 | 7,7 |
| 77 | R | 76 | 81 | 4.50 | 7,7 |
| 78 | | 76 | 80 | 3.63 | 7,7 |
| 79 | | 76 | 79 | 2.74 | 7,7 |
| 80 | F | 98 | 100 | 1.43 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 81 | | 98 | 101 | 2.13 | 7,7 |
| 82 | | 98 | 100 | 1.43 | 7,7 |
| 83 | T | 188 | 178 | 3.86 | 7,7 |
| 84 | | 188 | 178 | 3.86 | 7,7 |
| 85 | | 188 | 181 | 2.68 | 7,7 |
| 86 | E | 102 | 103 | 0.69 | 7,7 |
| 87 | | 102 | 106 | 2.72 | 7,7 |
| 88 | | 102 | 110 | 5.34 | 7,7 |
| 89 | D | 101 | 105 | 2.75 | 7,7 |
| 90 | | 101 | 108 | 4.74 | 7,7 |
| 91 | | 101 | 98 | 2.13 | 7,7 |
| 92 | A | 118 | 120 | 1.19 | 7,7 |
| 93 | | 118 | 120 | 1.19 | 7,7 |
| 94 | | 118 | 125 | 4.07 | 7,7 |
| 95 | H | 278 | 282 | 1.01 | 7,7 |
| 96 | | 278 | 301 | 5.62 | 7,7 |
| 97 | | 278 | 302 | 5.85 | 7,7 |
| 98 | DJ | 188 | 191 | 1.12 | 7,7 |
| 99 | | 188 | 194 | 2.22 | 7,7 |
| 100 | | 188 | 195 | 2.58 | 7,7 |
| 101 | W | 121 | 127 | 3.42 | 7,7 |
| 102 | | 121 | 129 | 4.53 | 7,7 |
| 103 | | 121 | 126 | 2.86 | 7,7 |
| 104 | N | 119 | 125 | 3.48 | 7,7 |
| 105 | | 119 | 127 | 4.60 | 7,7 |
| 106 | | 119 | 124 | 2.91 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 107 | D | 153 | 161 | 3.60 | 7,7 |
| 108 | | 153 | 167 | 6.19 | 7,7 |
| 109 | | 153 | 165 | 5.34 | 7,7 |
| 110 | R | 283 | 292 | 2.21 | 7,7 |
| 111 | | 283 | 295 | 2.94 | 7,7 |
| 112 | | 283 | 293 | 2.46 | 7,7 |
| 113 | M | 121 | 127 | 3.42 | 7,7 |
| 114 | | 121 | 126 | 2.86 | 7,7 |
| 115 | | 121 | 124 | 1.73 | 7,7 |
| 116 | I | 119 | 124 | 2.91 | 7,7 |
| 117 | | 119 | 125 | 3.48 | 7,7 |
| 118 | | 119 | 121 | 1.18 | 7,7 |
| 119 | H | 160 | 165 | 2.18 | 7,7 |
| 120 | | 160 | 167 | 3.03 | 7,7 |
| 121 | | 160 | 166 | 2.60 | 7,7 |
| 122 | S | 196 | 202 | 2.13 | 7,7 |
| 123 | | 196 | 205 | 3.17 | 7,7 |
| 124 | | 196 | 199 | 1.07 | 7,7 |
| 125 | D | 147 | 152 | 2.36 | 7,7 |
| 126 | | 147 | 155 | 3.75 | 7,7 |
| 127 | | 147 | 154 | 3.29 | 7,7 |
| 128 | R | 149 | 150 | 0.47 | 7,7 |
| 129 | | 149 | 152 | 1.41 | 7,7 |
| 130 | | 149 | 151 | 0.94 | 7,7 |
| 131 | T | 225 | 239 | 4.27 | 7,7 |
| 132 | | 225 | 240 | 4.56 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 133 | | 225 | 241 | 4.86 | 7,7 |
| 134 | A | 148 | 155 | 3.27 | 7,7 |
| 135 | | 148 | 153 | 2.35 | 7,7 |
| 136 | | 148 | 152 | 1.89 | 7,7 |
| 137 | D | 135 | 140 | 2.57 | 7,7 |
| 138 | | 135 | 143 | 4.07 | 7,7 |
| 139 | | 135 | 141 | 3.07 | 7,7 |
| 140 | S | 149 | 152 | 1.41 | 7,7 |
| 141 | | 149 | 150 | 0.47 | 7,7 |
| 142 | | 149 | 149 | 0.00 | 7,7 |
| 143 | T | 80 | 80 | 0.00 | 7,7 |
| 144 | | 80 | 82 | 1.75 | 7,7 |
| 145 | A | 92 | 94 | 1.52 | 7,7 |
| 146 | | 92 | 96 | 3.01 | 7,7 |
| 147 | H | 71 | 72 | 0.99 | 7,7 |
| 148 | | 71 | 74 | 2.93 | 7,7 |
| 149 | D | 105 | 106 | 0.67 | 7,7 |
| 150 | | 105 | 105 | 0.00 | 7,7 |

| | | | |
|---|---|---|---|
| AVERAGE | 130.36 | 135.30 | |
| MEAN | 118 | 115 | |
| SD | 64.29 | 70.41 | |
| CV % | 49.32 | 52.04 | 0.033 |
| Percent | | | |
| a. Lower (%) | | 15.33 | |
| b. Same (%) | | 2.67 | |

| | |
|---|---|
| C. Higher (%) | 81.33 |

D. CONCLUSION

Device DiVi Lab Optima 4 in 1 GCU-BP Meter and DiVi Lab Glucose Test Strip has met the performance criteria for point of care testing.

E. REFERENCE STANDARD

1. Pemantapan Mutu Eksternal Laboratorium Inaeqas (Badan Khusus Penyelenggara Pemantapan Mutu Eksternal Laboratorium di bawah Perhimpunan Dokter Spesialis Patologi Klinik dan Kedokteran Laboratorium Indonesia).
2. Siregar, M. T., Wulan, W. S., Setiawan, D., & Nuryati, A. (2018). Kendali Mutu: Bahan Ajar Teknologi Laboratorium Medik (TLM). Pusat Pendidikan Sumber Daya Manusia Kesehatan, Badan Pengembangan dan Pemberdayaan Sumber Daya Manusia Kesehatan, Kementerian Kesehatan Republik Indonesia.
3. Pourhoseingholi, M. A., Vahedi, M., & Rahimzadeh, M. (2013). Sample size calculation in medical studies. Gastroenterology and Hepatology from Bed to Bench, 6(1), 14-17. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4017493/

Bandung, 15st August 2025

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# EVALUATION OF
# DiVi LAB OPTIMA 4 IN 1 GCU-BP METER DEVICE FOR INSPECTION DiVi LAB CHOLESTEROL TEST STRIP IN RSAU dr M SALAMUN

A. AIM

This evaluation was done in RSAU dr. M. Salamun Pathology Laboratory, on July 2025, The aim of this evaluation is to assess the performance of reagent DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Cholesterol Test Strip.

B. EVALUATION SAMPLE

Sample was analyzed using Dialab Autolyser in RSAU dr. M. Salamun Pathology Laboratory, 150 samples collected from patient in RSAU dr. M. Salamun who are checked for DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Cholesterol Test Strip tested and being with chemistry autolyzer using samples.

C. RESULT

Sample was tested using reagent DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Cholesterol Test Strip, with result :

## CLINICAL TEST POCT DiVi Lab Optima 4 in 1 GCU-BP Meter

## PARAMETER : CHOLESTEROL (DiVi LAB CHOLESTEROL TEST STRIP)

LOT STRIP : 20250603

| NO | NAME | RSAU dr M SALAMUN | DiVi LAB OPTIMA 4 IN 1 GCU-BP METER DEVICE and DiVi LAB CHOLESTEROL TEST STRIP | CV % | CCV % |
|---|---|---|---|---|---|
| 1 | A | 198 | 217 | 6.47 | 7,6 |

| | | | | | |
|---|---|---|---|---|---|
| 2 | B | 215 | 228 | 4.15 | 7,6 |
| 3 | D | 191 | 213 | 7.70 | 7,6 |
| 4 | E | 226 | 236 | 3.06 | 7,6 |
| 5 | F | 189 | 205 | 5.74 | 7,6 |
| 6 | G | 196 | 213 | 5.88 | 7,6 |
| 7 | H | 213 | 221 | 2.61 | 7,6 |
| 8 | S | 192 | 198 | 2.18 | 7,6 |
| 9 | R | 161 | 158 | 1.33 | 7,6 |
| 10 | | 161 | 162 | 0.44 | 7,6 |
| 11 | D | 169 | 183 | 5.62 | 7,6 |
| 12 | | 169 | 179 | 4.06 | 7,6 |
| 13 | DJ | 149 | 157 | 3.70 | 7,6 |
| 14 | | 149 | 162 | 5.91 | 7,6 |
| 15 | S | 178 | 183 | 1.96 | 7,6 |
| 16 | | 178 | 180 | 0.79 | 7,6 |
| 17 | A | 141 | 130 | 5.74 | 7,6 |
| 18 | | 141 | 143 | 1.00 | 7,6 |
| 19 | D | 215 | 196 | 6.54 | 7,6 |
| 20 | | 216 | 197 | 6.51 | 7,6 |
| 21 | N | 238 | 243 | 1.47 | 7,6 |
| 22 | | 238 | 245 | 2.05 | 7,6 |
| 23 | I | 165 | 170 | 2.11 | 7,6 |
| 24 | | 165 | 175 | 4.16 | 7,6 |
| 25 | A | 135 | 135 | 0.00 | 7,6 |
| 26 | | 135 | 140 | 2.57 | 7,6 |
| 27 | A | 161 | 154 | 3.14 | 7,6 |

| | | | | | |
|---|---|---|---|---|---|
| 28 | | 161 | 157 | 1.78 | 7,6 |
| 29 | W | 145 | 151 | 2.87 | 7,6 |
| 30 | | 145 | 148 | 1.45 | 7,6 |
| 31 | N | 160 | 171 | 4.70 | 7,6 |
| 32 | | 160 | 162 | 0.88 | 7,6 |
| 33 | A | 248 | 257 | 2.52 | 7,6 |
| 34 | | 248 | 268 | 5.48 | 7,6 |
| 35 | R | 154 | 169 | 6.57 | 7,6 |
| 36 | | 155 | 170 | 6.53 | 7,6 |
| 37 | D | 158 | 166 | 3.49 | 7,6 |
| 38 | | 158 | 163 | 2.20 | 7,6 |
| 39 | J | 165 | 169 | 1.69 | 7,6 |
| 40 | | 165 | 174 | 3.75 | 7,6 |
| 41 | L | 130 | 134 | 2.14 | 7,6 |
| 42 | | 130 | 143 | 6.73 | 7,6 |
| 43 | M | 160 | 178 | 7.53 | 7,6 |
| 44 | | 161 | 179 | 7.49 | 7,6 |
| 45 | W | 191 | 205 | 5.00 | 7,6 |
| 46 | | 191 | 210 | 6.70 | 7,6 |
| 47 | D | 174 | 190 | 6.22 | 7,6 |
| 48 | | 175 | 191 | 6.18 | 7,6 |
| 49 | T | 198 | 212 | 4.83 | 7,6 |
| 50 | | 199 | 213 | 4.81 | 7,6 |
| 51 | F | 268 | 243 | 6.92 | 7,6 |
| 52 | | 268 | 253 | 4.07 | 7,6 |
| 53 | M | 178 | 183 | 1.96 | 7,6 |

| | | | | | |
|---|---|---|---|---|---|
| 54 | | 178 | 172 | 2.42 | 7,6 |
| 55 | M | 168 | 160 | 3.45 | 7,6 |
| 56 | | 168 | 157 | 4.79 | 7,6 |
| 57 | N | 152 | 151 | 0.47 | 7,6 |
| 58 | | 152 | 154 | 0.92 | 7,6 |
| 59 | T | 198 | 190 | 2.92 | 7,6 |
| 60 | | 198 | 187 | 4.04 | 7,6 |
| 61 | A | 209 | 229 | 6.46 | 7,6 |
| 62 | | 210 | 230 | 6.43 | 7,6 |
| 63 | | 209 | 199 | 3.47 | 7,6 |
| 64 | W | 178 | 188 | 3.86 | 7,6 |
| 65 | | 178 | 181 | 1.18 | 7,6 |
| 66 | | 178 | 172 | 2.42 | 7,6 |
| 67 | N | 197 | 216 | 6.51 | 7,6 |
| 68 | | 197 | 216 | 6.51 | 7,6 |
| 69 | | 198 | 217 | 6.47 | 7,6 |
| 70 | S | 148 | 150 | 0.95 | 7,6 |
| 71 | | 148 | 154 | 2.81 | 7,6 |
| 72 | | 148 | 153 | 2.35 | 7,6 |
| 73 | R | 195 | 212 | 5.91 | 7,6 |
| 74 | | 195 | 190 | 1.84 | 7,6 |
| 75 | | 195 | 211 | 5.57 | 7,6 |
| 76 | F | 116 | 122 | 3.57 | 7,6 |
| 77 | | 116 | 120 | 2.40 | 7,6 |
| 78 | | 116 | 117 | 0.61 | 7,6 |
| 79 | T | 285 | 302 | 4.10 | 7,6 |

| | | | | | |
|---|---|---|---|---|---|
| 80 | | 285 | 296 | 2.68 | 7,6 |
| 81 | | 285 | 287 | 0.49 | 7,6 |
| 82 | R | 245 | 226 | 5.70 | 7,6 |
| 83 | | 245 | 230 | 4.47 | 7,6 |
| 84 | | 246 | 231 | 4.45 | 7,6 |
| 85 | D | 179 | 181 | 0.79 | 7,6 |
| 86 | | 179 | 178 | 0.40 | 7,6 |
| 87 | | 179 | 175 | 1.60 | 7,6 |
| 88 | A | 168 | 161 | 3.01 | 7,6 |
| 89 | | 168 | 171 | 1.25 | 7,6 |
| 90 | | 168 | 179 | 4.48 | 7,6 |
| 91 | H | 197 | 198 | 0.36 | 7,6 |
| 92 | | 197 | 211 | 4.85 | 7,6 |
| 93 | | 197 | 216 | 6.51 | 7,6 |
| 94 | DJ | 186 | 198 | 4.42 | 7,6 |
| 95 | | 186 | 183 | 1.15 | 7,6 |
| 96 | | 186 | 197 | 4.06 | 7,6 |
| 97 | W | 175 | 186 | 4.31 | 7,6 |
| 98 | | 175 | 178 | 1.20 | 7,6 |
| 99 | | 175 | 177 | 0.80 | 7,6 |
| 100 | N | 196 | 215 | 6.54 | 7,6 |
| 101 | | 196 | 213 | 5.88 | 7,6 |
| 102 | | 196 | 213 | 5.88 | 7,6 |
| 103 | D | 180 | 199 | 7.09 | 7,6 |
| 104 | | 180 | 184 | 1.55 | 7,6 |
| 105 | | 180 | 186 | 2.32 | 7,6 |

| | | | | | |
|---|---|---|---|---|---|
| 106 | R | 268 | 289 | 5.33 | 7,6 |
| 107 | | 268 | 279 | 2.84 | 7,6 |
| 108 | | 268 | 285 | 4.35 | 7,6 |
| 109 | M | 162 | 161 | 0.44 | 7,6 |
| 110 | | 162 | 163 | 0.44 | 7,6 |
| 111 | | 162 | 158 | 1.77 | 7,6 |
| 112 | I | 196 | 204 | 2.83 | 7,6 |
| 113 | | 196 | 214 | 6.21 | 7,6 |
| 114 | | 196 | 211 | 5.21 | 7,6 |
| 115 | H | 155 | 159 | 1.80 | 7,6 |
| 116 | | 155 | 164 | 3.99 | 7,6 |
| 117 | | 155 | 154 | 0.46 | 7,6 |
| 118 | S | 192 | 208 | 5.66 | 7,6 |
| 119 | | 192 | 203 | 3.94 | 7,6 |
| 120 | | 192 | 205 | 4.63 | 7,6 |
| 121 | I | 170 | 187 | 6.73 | 7,6 |
| 122 | | 170 | 187 | 6.73 | 7,6 |
| 123 | | 170 | 175 | 2.05 | 7,6 |
| 124 | T | 138 | 144 | 3.01 | 7,6 |
| 125 | | 138 | 149 | 5.42 | 7,6 |
| 126 | | 138 | 151 | 6.36 | 7,6 |
| 127 | A | 171 | 165 | 2.53 | 7,6 |
| 128 | | 171 | 161 | 4.26 | 7,6 |
| 129 | | 171 | 161 | 4.26 | 7,6 |
| 130 | D | 152 | 169 | 7.49 | 7,6 |
| 131 | | 152 | 167 | 6.65 | 7,6 |

| | | | | | |
|---|---|---|---|---|---|
| 132 | | 152 | 154 | 0.92 | 7,6 |
| 133 | S | 143 | 145 | 0.98 | 7,6 |
| 134 | | 143 | 147 | 1.95 | 7,6 |
| 135 | | 143 | 154 | 5.24 | 7,6 |
| 136 | T | 106 | 110 | 2.62 | 7,6 |
| 137 | | 106 | 112 | 3.89 | 7,6 |
| 138 | A | 111 | 120 | 5.51 | 7,6 |
| 139 | | 111 | 119 | 4.92 | 7,6 |
| 140 | H | 170 | 182 | 4.82 | 7,6 |
| 141 | | 170 | 181 | 4.43 | 7,6 |
| 142 | D | 137 | 143 | 3.03 | 7,6 |
| 143 | | 137 | 139 | 1.02 | 7,6 |
| 144 | | 138 | 140 | 1.02 | 7,6 |
| 145 | M | 144 | 139 | 2.50 | 7,6 |
| 146 | | 144 | 140 | 1.99 | 7,6 |
| 147 | | 144 | 140 | 1.99 | 7,6 |
| 148 | R | 132 | 127 | 2.73 | 7,6 |
| 149 | | 132 | 126 | 3.29 | 7,6 |
| 150 | | 132 | 125 | 3.85 | 7,6 |

| | | | |
|---|---|---|---|
| AVERAGE | 177.09 | 182.78 | |
| MEAN | 171 | 178.5 | |
| SD | 37.42 | 39.13 | |
| CV % | 21.13 | 21.41 | 0.007 |
| Persent | | | |
| a. Lower (%) | | 24.67 | |

| | | |
|---|---|---|
| b. Same (%) | | 0.67 |
| C. Higher (%) | | 74.67 |

D. CONCLUSION

Device DiVi Lab Optima 4 in 1 GCU-BP Meter and DiVi Lab Cholesterol Test Strip has met the performance criteria for point of care testing.

E. REFERENCE STANDARD

1. Pemantapan Mutu Eksternal Laboratorium Inaeqas (Badan Khusus Penyelenggara Pemantapan Mutu Eksternal Laboratorium di bawah Perhimpunan Dokter Spesialis Patologi Klinik dan Kedokteran Laboratorium Indonesia).
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Bandung, 15st August 2025

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# EVALUATION OF
# DiVi LAB OPTIMA 4 IN 1 GCU-BP METER DEVICE FOR INSPECTION DiVi LAB URIC ACID TEST STRIP IN RSAU dr M SALAMUN

A. AIM

This evaluation was done in RSAU dr. M. Salamun Pathology Laboratory, on July 2025, The aim of this evaluation is to assess the performance of reagent DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Uric Acid Test Strip.

B. EVALUATION SAMPLE

Sample was analyzed using Dialab Autolyser in RSAU dr. M. Salamun Pathology Laboratory, 150 samples collected from patient in RSAU dr. M. Salamun who are checked for DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Uric Acid Test Strip tested and being with chemistry autolyzer using samples.

C. RESULT

Sample was tested using reagent DiVi Lab Optima 4 in 1 GCU-BP Meter device and DiVi Lab Uric Acid Test Strip, with result:

## CLINICAL TEST POCT DiVi LAB OPTIMA 4 IN 1 GCU-BP METER

## PARAMETER : URIC ACID (DiVi LAB URIC ACID TEST STRIP)

LOT STRIP : 20250512

| NO | NAME | RSAU dr M SALAMUN | DiVi LAB OPTIMA 4 IN 1 GCU-BP METER and DiVi LAB URIC ACID TEST STRIP | CV % | CCV % |
|---|---|---|---|---|---|
| 1 | A | 6.6 | 6.0 | 6.73 | 7,7 |
| 2 | C | 8.5 | 8.5 | 0.00 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 3 | D | 7.0 | 6.7 | 3.10 | 7,7 |
| 4 | F | 5.3 | 5.0 | 4.12 | 7,7 |
| 5 | G | 5.0 | 4.9 | 1.43 | 7,7 |
| 6 | S | 7.1 | 7.3 | 1.96 | 7,7 |
| 7 | R | 3.7 | 4.0 | 5.51 | 7,7 |
| 8 | | 3.7 | 3.8 | 1.89 | 7,7 |
| 9 | D | 4.0 | 4.2 | 3.45 | 7,7 |
| 10 | | 4.0 | 4.2 | 3.45 | 7,7 |
| 11 | K | 7.2 | 7.5 | 2.89 | 7,7 |
| 12 | | 7.2 | 7.0 | 1.99 | 7,7 |
| 13 | DJ | 7.3 | 7.5 | 1.91 | 7,7 |
| 14 | | 7.3 | 7.4 | 0.96 | 7,7 |
| 15 | S | 7.6 | 7.8 | 1.84 | 7,7 |
| 16 | | 7.6 | 7.7 | 0.92 | 7,7 |
| 17 | A | 11.8 | 12.3 | 2.93 | 7,7 |
| 18 | | 11.8 | 12.3 | 2.93 | 7,7 |
| 19 | D | 6.6 | 6.7 | 1.06 | 7,7 |
| 20 | | 6.6 | 6.5 | 1.08 | 7,7 |
| 21 | N | 6.7 | 6.6 | 1.06 | 7,7 |
| 22 | | 6.7 | 6.5 | 2.14 | 7,7 |
| 23 | I | 6.1 | 6.1 | 0.00 | 7,7 |
| 24 | | 6.1 | 5.9 | 2.36 | 7,7 |
| 25 | A | 6.8 | 7.4 | 5.98 | 7,7 |
| 26 | | 6.8 | 6.9 | 1.03 | 7,7 |
| 27 | A | 3.7 | 4.1 | 7.25 | 7,7 |
| 28 | | 3.7 | 4 | 5.51 | 7,7 |

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|---|---|---|---|---|---|
| 29 | W | 5.2 | 5.4 | 2.67 | 7,7 |
| 30 | | 5.2 | 5.7 | 6.49 | 7,7 |
| 31 | N | 4.3 | 4.1 | 3.37 | 7,7 |
| 32 | | 4.3 | 4.1 | 3.37 | 7,7 |
| 33 | A | 7.2 | 7.5 | 2.89 | 7,7 |
| 34 | | 7.2 | 7.5 | 2.89 | 7,7 |
| 35 | R | 7.8 | 8.1 | 2.67 | 7,7 |
| 36 | | 7.8 | 8.2 | 3.54 | 7,7 |
| 37 | D | 7.7 | 8.1 | 3.58 | 7,7 |
| 38 | | 7.7 | 7.9 | 1.81 | 7,7 |
| 39 | J | 4.0 | 4.4 | 6.73 | 7,7 |
| 40 | | 4.0 | 4.4 | 6.73 | 7,7 |
| 41 | L | 4.7 | 4.8 | 1.49 | 7,7 |
| 42 | | 4.7 | 5.1 | 5.77 | 7,7 |
| 43 | M | 7.9 | 7.7 | 1.81 | 7,7 |
| 44 | | 7.9 | 7.6 | 2.74 | 7,7 |
| 45 | W | 4.5 | 4.8 | 4.56 | 7,7 |
| 46 | | 4.5 | 4.8 | 4.56 | 7,7 |
| 47 | A | 12.8 | 12.0 | 4.56 | 7,7 |
| 48 | | 12.8 | 12.3 | 2.82 | 7,7 |
| 49 | D | 4.0 | 4.1 | 1.75 | 7,7 |
| 50 | | 4.0 | 3.9 | 1.79 | 7,7 |
| 51 | T | 5.6 | 5.1 | 6.61 | 7,7 |
| 52 | | 5.6 | 5.3 | 3.89 | 7,7 |
| 53 | F | 3.9 | 4.0 | 1.79 | 7,7 |
| 54 | | 3.9 | 4.0 | 1.79 | 7,7 |

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|---|---|---|---|---|---|
| 55 | M | 5.4 | 5.5 | 1.30 | 7,7 |
| 56 | | 5.4 | 4.9 | 6.87 | 7,7 |
| 57 | M | 5.6 | 5.7 | 1.25 | 7,7 |
| 58 | | 5.6 | 5.4 | 2.57 | 7,7 |
| 59 | N | 5.7 | 6.1 | 4.79 | 7,7 |
| 60 | | 5.7 | 6.3 | 7.07 | 7,7 |
| 61 | T | 6.3 | 6.4 | 1.11 | 7,7 |
| 62 | | 6.3 | 6.4 | 1.11 | 7,7 |
| 63 | A | 7.0 | 7.2 | 1.99 | 7,7 |
| 64 | | 7.0 | 7.3 | 2.97 | 7,7 |
| 65 | | 2.7 | 2.9 | 5.05 | 7,7 |
| 66 | M | 10.8 | 11.0 | 1.30 | 7,7 |
| 67 | | 10.8 | 11.1 | 1.94 | 7,7 |
| 68 | | 10.8 | 11.1 | 1.94 | 7,7 |
| 69 | S | 7.0 | 7.2 | 1.99 | 7,7 |
| 70 | | 7.0 | 7.4 | 3.93 | 7,7 |
| 71 | | 7.0 | 7.6 | 5.81 | 7,7 |
| 72 | R | 5.3 | 5.4 | 1.32 | 7,7 |
| 73 | | 5.3 | 5.8 | 6.37 | 7,7 |
| 74 | | 5.3 | 5.8 | 6.37 | 7,7 |
| 75 | F | 5.8 | 5.3 | 6.37 | 7,7 |
| 76 | | 5.8 | 5.4 | 5.05 | 7,7 |
| 77 | | 5.8 | 5.3 | 6.37 | 7,7 |
| 78 | T | 9.2 | 9.3 | 0.76 | 7,7 |
| 79 | | 9.2 | 9.1 | 0.77 | 7,7 |
| 80 | | 9.2 | 9.6 | 3.01 | 7,7 |

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|---|---|---|---|---|---|
| 81 | E | 5.9 | 6 | 1.19 | 7,7 |
| 82 | | 5.9 | 5.8 | 1.21 | 7,7 |
| 83 | | 5.9 | 5.8 | 1.21 | 7,7 |
| 84 | | 8.3 | 8.9 | 4.93 | 7,7 |
| 85 | | 8.3 | 8.9 | 4.93 | 7,7 |
| 86 | A | 4.1 | 4.3 | 3.37 | 7,7 |
| 87 | | 4.1 | 4.3 | 3.37 | 7,7 |
| 88 | | 4.1 | 4.3 | 3.37 | 7,7 |
| 89 | H | 9.0 | 8.6 | 3.21 | 7,7 |
| 90 | | 9.0 | 9.2 | 1.55 | 7,7 |
| 91 | | 9.0 | 9.1 | 0.78 | 7,7 |
| 92 | DJ | 7.4 | 7.8 | 3.72 | 7,7 |
| 93 | | 7.4 | 7.6 | 1.89 | 7,7 |
| 94 | | 7.4 | 7.5 | 0.95 | 7,7 |
| 95 | W | 6.7 | 7.4 | 7.02 | 7,7 |
| 96 | | 6.7 | 7.3 | 6.06 | 7,7 |
| 97 | | 6.7 | 7.1 | 4.10 | 7,7 |
| 98 | N | 8.5 | 8.9 | 3.25 | 7,7 |
| 99 | | 8.5 | 8.6 | 0.83 | 7,7 |
| 100 | | 8.5 | 8.9 | 3.25 | 7,7 |
| 101 | D | 7.0 | 7.3 | 2.97 | 7,7 |
| 102 | | 7.0 | 7.0 | 0.00 | 7,7 |
| 103 | | 7.0 | 7.5 | 4.88 | 7,7 |
| 104 | R | 3.5 | 3.4 | 2.05 | 7,7 |
| 105 | | 3.5 | 3.5 | 0.00 | 7,7 |
| 106 | | 3.5 | 3.5 | 0.00 | 7,7 |

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|---|---|---|---|---|---|
| 107 | M | 4.3 | 4.2 | 1.66 | 7,7 |
| 108 | | 4.3 | 3.9 | 6.90 | 7,7 |
| 109 | | 4.3 | 4.0 | 5.11 | 7,7 |
| 110 | I | 8.5 | 8.3 | 1.68 | 7,7 |
| 111 | | 8.5 | 8.6 | 0.83 | 7,7 |
| 112 | | 8.5 | 8.9 | 3.25 | 7,7 |
| 113 | H | 6.7 | 6.9 | 2.08 | 7,7 |
| 114 | | 6.7 | 6.8 | 1.05 | 7,7 |
| 115 | | 6.7 | 6.9 | 2.08 | 7,7 |
| 116 | S | 8.4 | 8.8 | 3.29 | 7,7 |
| 117 | | 8.4 | 8.9 | 4.09 | 7,7 |
| 118 | | 8.4 | 8.9 | 4.09 | 7,7 |
| 119 | D | 8.5 | 8.6 | 0.83 | 7,7 |
| 120 | | 8.5 | 8.9 | 3.25 | 7,7 |
| 121 | | 8.5 | 8.6 | 0.83 | 7,7 |
| 122 | R | 5.4 | 5.5 | 1.30 | 7,7 |
| 123 | | 5.4 | 5.3 | 1.32 | 7,7 |
| 124 | | 5.4 | 5.3 | 1.32 | 7,7 |
| 125 | T | 6.4 | 6.8 | 4.29 | 7,7 |
| 126 | | 6.4 | 6.9 | 5.32 | 7,7 |
| 127 | | 6.4 | 7.1 | 7.33 | 7,7 |
| 128 | A | 3.6 | 4.1 | 9.18 | 7,7 |
| 129 | | 3.6 | 3.9 | 5.66 | 7,7 |
| 130 | | 3.6 | 3.9 | 5.66 | 7,7 |
| 131 | D | 4.3 | 4.7 | 6.29 | 7,7 |
| 132 | | 4.3 | 4.5 | 3.21 | 7,7 |

| | | | | | |
|---|---|---|---|---|---|
| 133 | | 4.3 | 4.7 | 6.29 | 7,7 |
| 134 | S | 4.6 | 4.8 | 3.01 | 7,7 |
| 135 | | 4.6 | 4.9 | 4.47 | 7,7 |
| 136 | | 4.6 | 4.9 | 4.47 | 7,7 |
| 137 | T | 5.1 | 5.0 | 1.40 | 7,7 |
| 138 | | 5.1 | 5.1 | 0.00 | 7,7 |
| 139 | A | 4.6 | 4.4 | 3.14 | 7,7 |
| 140 | | 4.6 | 4.6 | 0.00 | 7,7 |
| 141 | H | 5.7 | 5.4 | 3.82 | 7,7 |
| 142 | | 5.7 | 5.6 | 1.25 | 7,7 |
| 143 | D | 8.8 | 8.9 | 0.80 | 7,7 |
| 144 | | 8.8 | 9.0 | 1.59 | 7,7 |
| 145 | M | 4.3 | 4.7 | 6.29 | 7,7 |
| 146 | | 4.3 | 4.5 | 3.21 | 7,7 |
| 147 | | 4.3 | 4.7 | 6.29 | 7,7 |
| 148 | R | 8.5 | 8.6 | 0.83 | 7,7 |
| 149 | | 8.5 | 8.9 | 3.25 | 7,7 |
| 150 | | 8.5 | 8.6 | 0.83 | 7,7 |

| | | | |
|---|---|---|---|
| AVERAGE | 6.40 | 6.54 | |
| MEAN | 6.4 | 6.45 | |
| SD | 2.03 | 2.06 | |
| CV % | 31.70 | 31.43 | 0.003 |
| Percent | | | |
| a. Lower (%) | | 27.33 | |
| b. Same (%) | | 3.33 | |

| | | |
|---|---|---|
| c. Higher (%) | | 68.67 |

D. CONCLUSION

Device DiVi Lab Optima 4 in 1 GCU-BP Meter and DiVi Lab Uric Acid Test Strip has met the performance criteria for point of care testing.

E. REFERENCE STANDARD

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Bandung, 15st August 2025

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