Accuracy of POCT device, Afinion™, for tests for diabetes and dyslipidemia

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ABSTRACT
Objective: The aim was to evaluate the analytical performance of a point of care system, based on boron affinity chromatography, for recommended laboratory tests for monitoring of diabetes and lipids e.g. Hemoglobin A1c and lipid profile tests.

Materials and Methods: The Afinion™ system (Afinion) is intended for use as POCT (Point Of Care Testing). It is a fully automated boronate affinity assay. Ten samples for HbA1c, CRP and Lipids (Total Cholesterol, HDL-C, LDL-C and Triglycerides) were analyzed on the Afinion™ system and chemistry analyzer Cobas 6000 for comparison. Cobas 6000 is a fully automated chemistry analyzer from Roche Diagnostics. The analyzer uses NGSP traceable, immunoturbidimetry based method and lipids by standard photometric methods traceable to reference respective methods. Five samples were also tested in duplicate to check imprecision for each of the tests. The percentage bias for each of the tests was evaluated using Total Error Allowable (TEA) based on biological variation.

Results: The bias percentage was 1.643% for HbA1c, -2.764% for CRP, 1.439% for Total Cholesterol, -1.794% for HDL Cholesterol, 3.013% for LDL cholesterol, 3.473% for Triglycerides as compared to those on Cobas 6000.

Conclusion: The strong correlations of HbA1c, CRP and Lipid profile performed on POCT with state of art automated chemistry analyzer indicate that the POCT can be used for monitoring of treatment at sites remote from the central laboratory with confidence. This can result in a faster turnaround time, prevent sample integrity issues as well as save transport costs. Accurate check of a new point of care system (Afinion TM AS100 Analyzer, Axis-Shield PoC, AS, Oslo, N) prior to consideration for procurement was to evaluate usability of the device for a small physician-office type of laboratory.

Keywords: point of care testing, diabetes, dyslipidemia

INTRODUCTION
Accuracy check of a new point of care system (Afinion TM AS100 Analyzer, Axis-Shield PoC, AS, Oslo, N) prior to consideration for procurement was to evaluate usability of the device for a small physician-office type of laboratory.

POCT is defined as medical testing at or near the site of patient care. The driving notion behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician and care team will receive the results quicker, which allows for immediate clinical management decisions to be made.

The device is designed for measurement of CRP, HbA1c, Total Cholesterol, HDL-C, LDL-C and Triglycerides.

The device employs boronate affinity chromatography principle. Limited number of samples were collected, analyzed in the device and compared to that of COBAS 6000, a fully automated device to evaluate the accuracy of the POCT device.

The Afinion™ AS100 Analyzer is designed to enable simple and fast on-the-spot testing, regardless of the sample type, which may be whole blood, plasma or urine, and to deliver accurate results during patient consultation for improved patient management.
 MATERIALS AND METHODS
All the assays on Afinion™ were compared to those on c501 of Cobas 6000 using patient samples. Cobas 6000 is currently used by the laboratory for chemistry and immunoassay testing. The laboratory uses two levels of internal quality controls of Roche and participates in CAP proficiency testing program.

The results obtained by both the analyzers were compared using bias plot. Bias plots were prepared by plotting Afinion values for each test on X-axis and percentage difference of obtained value minus Cobas values on Y-axis. Total Allowable Error [TE (a)] for each assay was based on CLIA Limits (Clinical Laboratory Improvement (amendment) Act, 1988). Bias was calculated as percentage by comparing obtained results with those of Cobas 6000 [(Value-Afinion – Value-Cobas) /Value-Cobas]*100. Acceptance criteria for allowable bias were considered as TE (a)/3. Percentage bias of all samples was averaged for each of the test and compared to TE (a)/3 for acceptance.

Samples received in the laboratory on routine basis from out-patients for HbA1c, CRP and Lipids tests were utilized for partial validation. No sample was collected specifically for validation.

Samples were selected on the basis of (a) adequacy of sample volume (b) low to high values (as compared to reference interval used by the laboratory) and (c) Sample integrity.

Ten samples of K3 EDTA and serum were utilized for the tests. All samples were obtained immediately after analysis was over, on the COBAS 6000, for the all the requested tests. The test details are as follows (Table 1).

The result of HbA1c values of selected samples varies from 6 – 12% and that of CRP was from 6 – 100 mg/dl. The results of Total Cholesterol were in the range of 110 – 270 mg/dl, HDL from 30 – 70mg/dl, Triglycerides from 90 – 280 mg/dl and LDL from 70 – 190 mg/dl

One cartridge is used for one sample for each type of the test. The cartridge comprises of sampling device and reagent container. The cartridges were allowed to reach room temperature. All samples were aspirated using sampling device. The cartridge was loaded into the reader after charging the sample. After incubation time as per assay design the result was generated using lot specific stored calibration. The test cartridge contained all reagents necessary for the measurement of specific tests.

The method of measurement of HbA1c is traceable to IFCC reference method and reports DCCT/UKPDS aligned values. Afinion™ CRP is standardized against the IFCC/BRC/CAP protein reference

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sample type</th>
<th>Principle</th>
<th>Sample Volume</th>
<th>Assay Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRP</td>
<td>Serum/Heparin Plasma</td>
<td>Immunometric membrane flow</td>
<td>1.5 µl</td>
<td>4 minutes</td>
</tr>
<tr>
<td></td>
<td>EDTA</td>
<td>Boronate affinity</td>
<td>1.5 µl</td>
<td>3 minutes</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Citrate/Heparin</td>
<td>Chromatography Enzymatic colorimetric method</td>
<td>15 µl</td>
<td>8 minutes</td>
</tr>
<tr>
<td>Lipid Profile</td>
<td>Serum/Heparinized Plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

Limited accuracy check for Afinion is acceptable. Each assay has traceability to reference method and the analyzer could be subjected to the same stringent quality criteria for accuracy check commonly applied to fully automated analyzers if we extrapolate the data. If precision is found acceptable, the assays could be employed for monitoring of patients on treatment for the assays available.

The major limitation of the study is unavailability of data on precision.

CONCLUSION

Afinion Analyzer gives reliable results which can be conveniently obtained at physician office or at small satellite laboratory. This provides benefits of faster turnaround time, better sample integrity as well as saving on transport costs.

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RESULTS

<table>
<thead>
<tr>
<th>Sr.</th>
<th>Assay</th>
<th>%Bias</th>
<th>Acceptance Limit (%)</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>CRP</td>
<td>-2.764</td>
<td>7.5</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2.</td>
<td>HbA1c</td>
<td>1.643</td>
<td>1.750</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3.</td>
<td>Total Cholesterol</td>
<td>1.439</td>
<td>2.500</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4.</td>
<td>HDL Cholesterol</td>
<td>-1.794</td>
<td>4.250</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5.</td>
<td>LDL Cholesterol</td>
<td>3.013</td>
<td>4.000</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

Table 2: Acceptability range calculated for each assay
REFERENCES

