

## **Point of Care Testing (POCT) of Antipsychotic Drugs**

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**Introduction-Aims:** Treatment guidelines, clinical support tools, and expert consensus guidelines recommend measurement of antipsychotic blood levels, as adherence to antipsychotic therapy is critical to positive treatment outcomes. POCT provides immediate, objective drug level results during the patient visit so clinicians can provide personalized treatment plans to combat problems such as nonadherence, pharmacokinetic interactions (drug-drug, changes in lifestyle), poor response, or unacceptable toxicity. The aims of the study were to validate a whole blood (WB) POCT assay for clozapine (CLZ) and to develop WB POCT assays for total aripiprazole (aripiprazole + major metabolite dehydroaripiprazole; ARI), and total risperidone (risperidone + major metabolite 9-hydroxyrisperidone; RSP). **Methods:** Automated homogenous immunoassays (MyCare™ Psychiatry assay kits for Clozapine (CE Mark/US), Total Aripiprazole (CE Mark), and Total Risperidone (CE Mark)) used to measure CLZ, ARI, and RSP, respectively, were modified to test analyte levels in WB with a MyCare Insite, a small, portable analyser used for rapid POCT. Analytical performance of MyCare Insite Clozapine Test (CLZ-POCT) was evaluated according to CLSI guidelines with 3 reagent lots while ARI-POCT and RSP-POCT were evaluated using scaled-up reagents. Testing was performed on MyCare Insites using buffered controls and spiked WB samples. **Results:** The CLZ-POCT was linear from 175 – 1,390 ng/mL. Within-laboratory precision over measuring range was 8.5 – 16.5%. The limit of quantification (LoQ) was 175 ng/mL. No bias from hematocrit (35 – 50%) was observed. The percent recovery over the measuring range was 82 – 108%. CLZ-POCT Insite results from 304 patient samples were compared to a validated LC-MS/MS; Passing-Bablok regression analysis statistics: 0.97 (slope), -21 (intercept), and 0.9 (R). The ARI-POCT was linear from 56 – 1,000 ng/mL. Within-laboratory precision over the measuring range was 7.3 – 11.2%. The percent recovery over the measuring range was 82 – 115%. The RSP-POCT percent recovery from 15 to 120 ng/mL was 95 – 110%. **Conclusions:** Precise, accurate blood levels of the antipsychotics clozapine, aripiprazole, and risperidone can be reported in less than 8 minutes using capillary human whole blood samples at point of care.