# TITLE: Qualitative Test Validation

**PRINICPLE:** To validate the cut-off values for the Drugs of Abuse and Infectious Disease Qualitative Tests.

**REAGENTS AND EQUIPMENT:**

1. Abbott Architect ci8200 and ci4100 analyzer
2. Reagent packs for the Drugs of Abuse and Infectious Disease Tests
3. Abbott’s Assay Specific Calibrators
4. Bio-Rad Controls S1E and S2E for Drugs of Abuse testing
5. Bio-Rad Viroclear, Virotrol I, Virotrol III, Virotrol HIV-1 AG, Virotrol HIV-2, Virotrol HIV-1 Ag and Syphilis for Infectious Disease testing

**STEPWISE PROCEDURE:**

1. The cutoffs for the Drugs of Abuse and Infectious Disease testing were verified initially by Abbott Architect Field Service and Implementation team.
2. The Drugs of Abuse and Infectious Disease tests are calibrated at least every six months, when we receive a new lot of Reagent, after major service to the instrument or when the Positive and Negative QC material is outside the acceptable range.

NOTE: Positive and Negative controls are run daily. The Controls and Calibrators are all near the cut-off values.

**RESULTS:**

Drugs of Abuse:

The results we report are for medical (i.e. treatment) purposes only.

Drug Class Cut-off

Amphetamine 1000 ng/mL

Barbiturate 200 ng/mL

Benzodaizepine 200 ng/mL

Cannabinoid 50 ng/mL

Cocaine 300 ng/L

Opiate 2000 ng/mL

PCP 25 ng/mL

Infectious Diseases:

Test Cut-off

Hepatitis C >1.0 S/CO (0.80-0.99 =Grayzone)

Hepatitis Core IgM >1.21 S/CO (0.80-1.21=Grayzone)

Hepatitis A IgM >1.21 S/CO (0.8-1.21=Grayzone)

Hepatitis B surface antigen >1.0 S/CO

HIV Ag/AB Rapid Combo >1.0 S/CO

Syphilis >1.0 S/CO

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