4th HEPATITIS C TECHNICAL ADVISORY GROUP

TAG Meeting

XPERT® HCV VL ASSAY PERFORMANCE EVALUATION

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Evaluation of the diagnostic performance of the Xpert® Fingerstick HCV Viral Load (VL) Assay

The Objective

- To conduct an evaluation of the Xpert HCV VL assay in resource-limited settings using operators with minimal to no laboratory experience.
- The Xpert HCV VL assay was compared to results from the Abbott RealTime HCV assay, an established CE marked assay.

Study activities workflow

Physician obtains IC from Patients

Physician record appropriate Information on CRF

Delink patient identifiers

Sample collection: 10 ml EDTA blood

Centrifuge the blood and separate plasma

Aliquot 1.1 ml plasma into tubes

Transfer 1.1 ml of plasma in to the HCV VL cartridge

Load the cartridge in to the instrument and start the assay

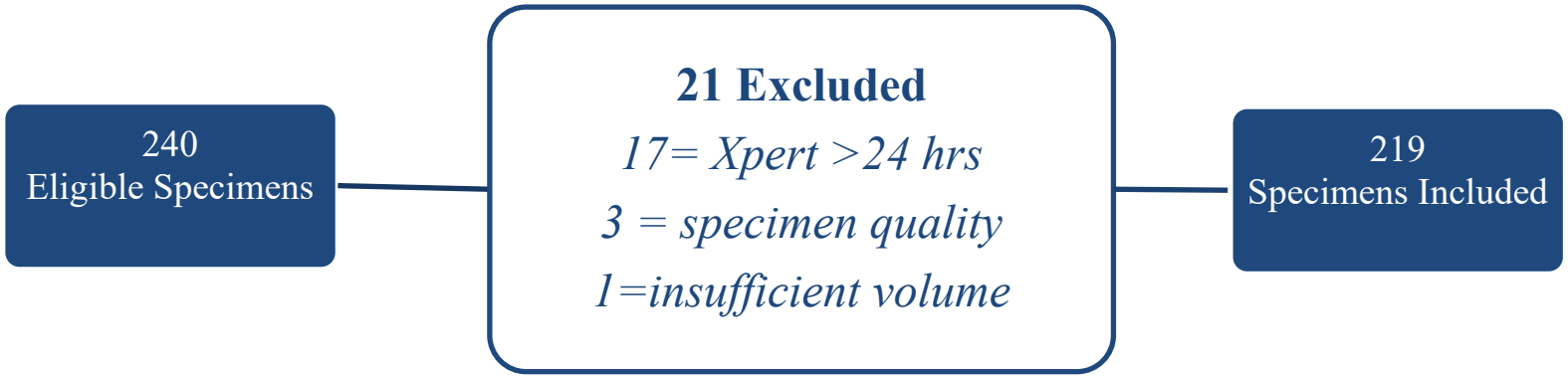
Store the remaining plasma 4 C at site in case re-testing id required

Within 6 hours ship to Lugar Center for reference testing

Study enrolment overview

- A total of 240 fresh samples were collected from subjects suspected of HCV infection or known HCV-Infected individuals
- All samples are tested on the Xpert®HCV VL assay at the two selected sites by the operators with minimal laboratory experience:
  - National Center for Disease Control and Public Health (NCDC) and
  - Center for Mental Health and Prevention of addiction
- All the samples were retested in parallel using Abbott HCV VL assay at the reference site, Lugar Center.

Study Specimen Accountability



Participant demographic description

# of participants	219
Age, years	46.5 (20-84)
Female sex, %	24.7% (54/219)
Male sex,%	75.3% (165/219)

- Of the 219 specimens included in the data analyses, 54 (24.7%) were collected from female subjects and 165 75.3%) from male subjects.
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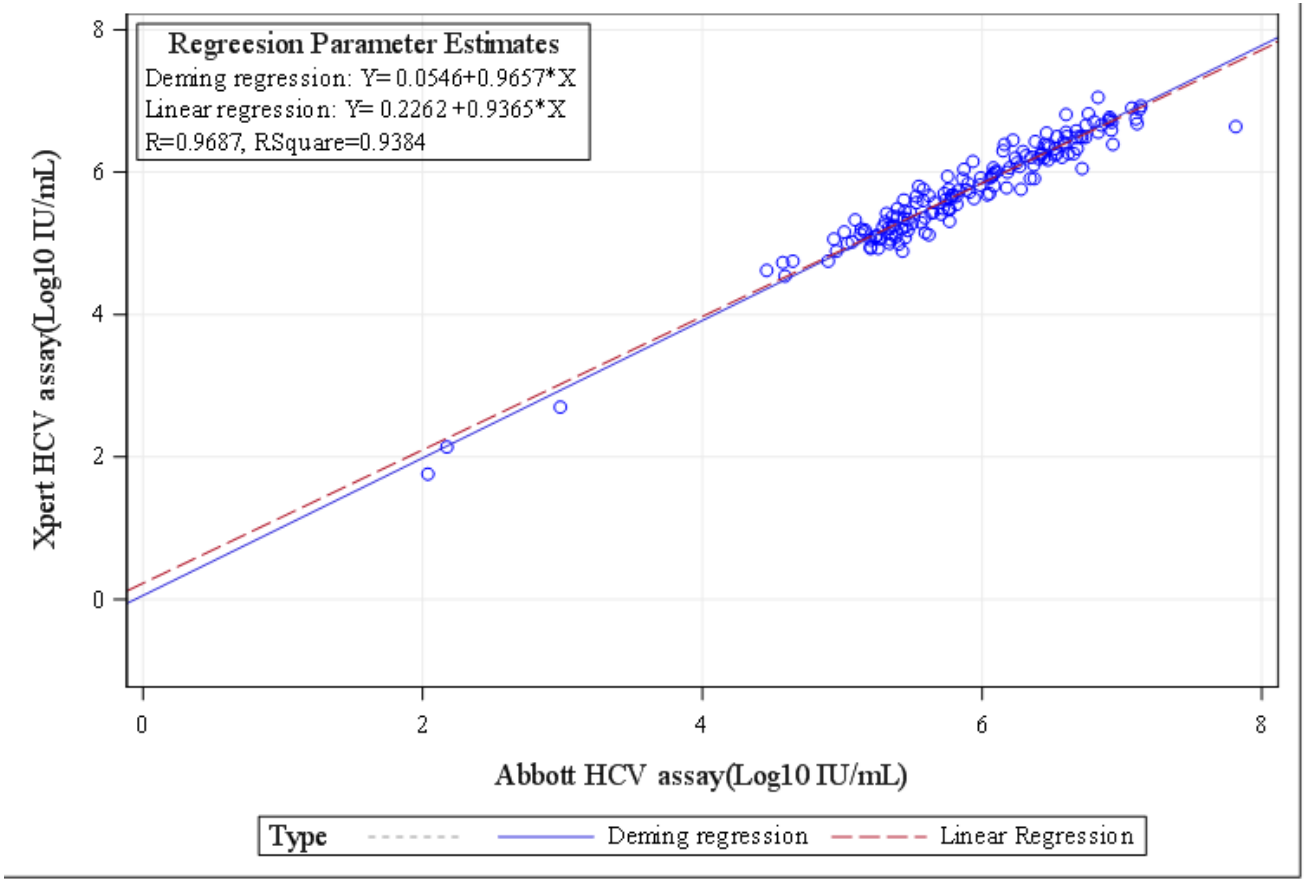
- The average age among subjects included in the data analyses was 46.5 ± 12.0 years, with a range of 20 to 84 years.

- Of these 219 specimens, 162 were within the quantitation range of the both the Xpert HCV VL assay and the Abbott RealTime HCV assay.

Comparison of HCV RNA results between Abbott and Xpert assay

		Abbott RealTime-HCV Assay			
		HCV Detected ≥12 IU/mL	HCV Detected <12 IU/mL	HCV Not Detected	Total
Xpert HCV VL	HCV Detected ≥10 IU/mL	162	0	0	162
	HCV Detected <10 IU/mL	0	2	3	5
	HCV Not Detected	0	1	51	52
	Total	162	3	54	219

Correlation of Xpert HCV VL Assay vs Abbott RealTime HCV Assay



CONCLUSION

- The Xpert HCV assay as a point-of-care molecular test, demonstrated excellent performance in in resource-limited settings using operators with minimal laboratory experience as compared to Abbott HCV VL test.
- The Xpert HCV VL assay tests for 96.8% (212/219) of the eligible specimens were successful on the first attempt
- The indeterminate cases included 6 ERROR and 1 INVALID. All 7 indeterminate cases yielded valid results upon repeat testing
- The overall rate of assay success was 100.0% (219/219). The overall indeterminate rate was 0.0%.
- Results of the study show that the Xpert® HCV VL assay is more easy to use and has a higher potential to be utilized in decentralized settings

Acknowledgement

- **Study participants**
- **Cepheid**
- **Study sites**
  - NCDC, Lugar Center
  - Center for Mental Health and Prevention of addiction