Implementation of HCV RNA testing at a Local Public Health Laboratory

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BACKGROUND

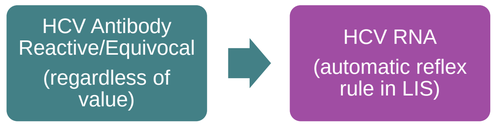
In October 2020, the Orange County Public Health Laboratory (OCPHL) implemented molecular testing for detection and quantitation of Hepatitis C virus (HCV) RNA on the Hologic Panther instrument to align with CDC recommendations to follow all reactive HCV Antibody test results with an HCV RNA test to identify current infections (Fig. 1).

In collaboration with the California Department of Public Health, University of California San Francisco, Orange County Communicable Disease Control, Orange County Jails, and Radiant Health Center, OCPHL used HCV testing and linkage to care CDC grant funding to expand testing in our community. Orange County was selected due to HCV screen positivity of ~20% in inmates.

The submitters tested during this study period included county Jails, county clinics (HIV, STI), employee health, coroners, and other county clients.

The issues before implementation included cost, serum processing, workflow, and assay stability limitations on the Panther. Blood specimens for HCV RNA require centrifugation within 6 hours of collection, which was a limitation for the jail clients. Additionally, there were delays interfacing the OCPHL LIS with the jail electronic health record system for test results.

Fig. 1 OCPHL workflow



METHODS

- Specimens: Serum (and Plasma for verification only)
- Test methods
  - HCV Antibody: Hepatitis C Antibody CMIA (Abbott Architect & Alinity i)
  - HCV RNA: Aptima HCV Quant Dx TMA Assay (Hologic Panther)
    - The assay aids in diagnosing active HCV infection and management of HCV infected patients undergoing HCV antiviral drug therapy.
- HCV RNA Verification Study on 2 Panther instruments
  - Manufacturer provided serum and plasma (w/EDTA) panels.
  - Accuracy and precision were evaluated.
- Serum Stability Study – Per the HCV RNA package insert, serum must be centrifuged within 6-hours of collection.
  - Submitters are not able to centrifuge HCV Antibody specimens within 6-hours of collection.
  - To accommodate the maximum number of days between specimen collection and receipt at the lab (weekends, holidays), stability was tested by centrifuging on day 5. Serum was held at 2-8°C.

Fig. 3 Number of specimens tested by HCV Antibody and HCV RNA during study period.

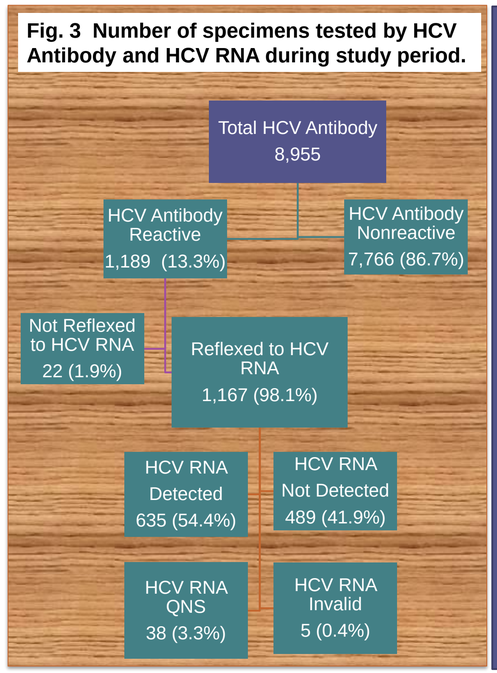


Fig. 4 Jail HCV Antibody October 2020-February 2022 n = 4,458

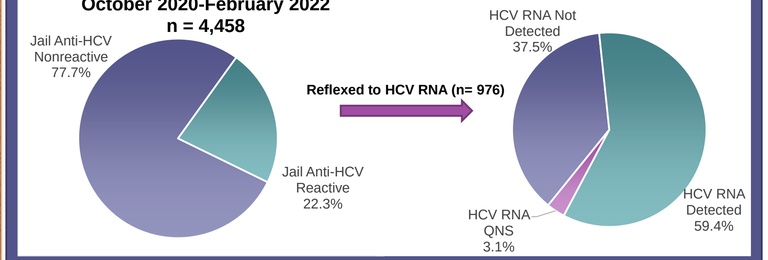
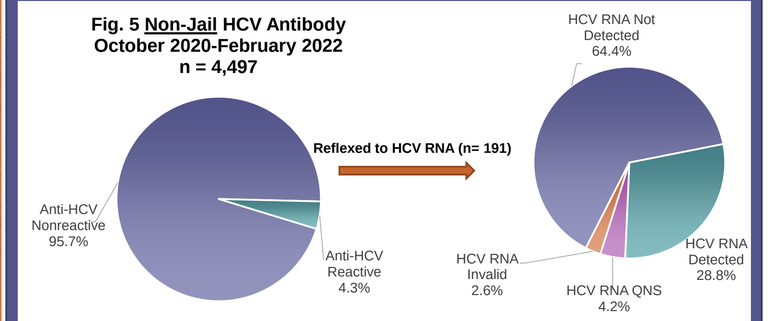


Fig. 5 Non-Jail HCV Antibody October 2020-February 2022 n = 4,497



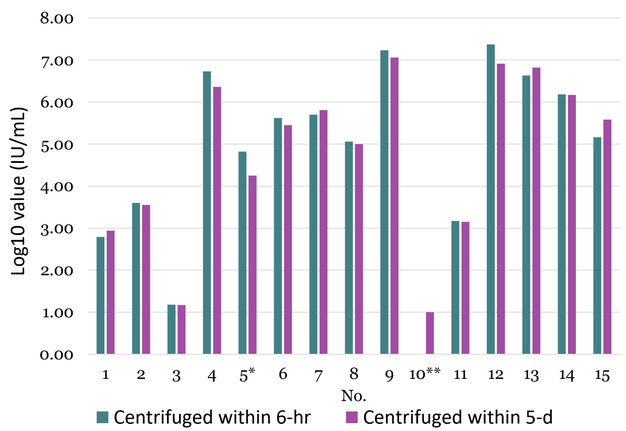
HCV RNA Verification Results

- Serum accuracy was 98% & 100% on each Panther instrument.
- Plasma accuracy was 93% for both instruments.
- Intra- and Inter-run precision were within a standard deviation of 0.25 Log10 IU/mL.
- The assay met the acceptance criteria for linearity (reference range).
- Reportable range per package insert:
  - <10-100,000,000 IU/mL (<1.00-8.00 Log10 IU/mL)
  - There were no samples over the UloQ

Serum Stability Study Results (Fig. 2)

- Twenty-three paired serum blood samples, one centrifuged within 6-hours and the second within 5 days of collection, were tested with the HCV RNA assay.
- Twenty-two of 23 sets (95.7%) had comparable results when tested in parallel on the HCV RNA assay.
- All HCV RNA "not-detected" results (N=8) agreed between the 6-hr and 5-d centrifuge.

Fig. 2 HCV Quant RNA Serum Stability Study n= 15 HCV RNA-Detected

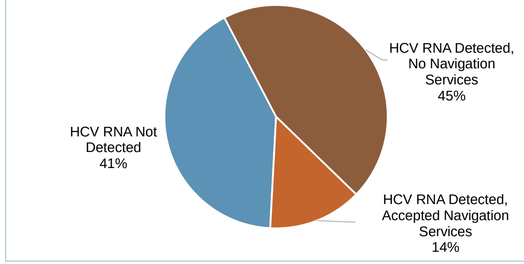


*SD was >0.25 Log10 IU/mL (4.82, 4.25)
**RNA was not detected at 6-hr centrifugation.

RESULTS

- Majority of specimens were from jails (50%) and county HIV/STI clinics (48%). Data included some patients that had more than one specimen collected due to follow-up.
- Overall, 98.1% of HCV Antibody reactive specimens were reflexed to HCV RNA; 54.4% had detectable levels of HCV RNA (Fig. 3).
- The percentage of jail specimens positive for HCV antibody was 22.3%; 59.4% confirmed by HCV RNA (Fig. 4).
- The percentage of non-jail specimens positive for HCV antibody was 4.3%; 28.8% confirmed by HCV RNA (Fig. 5).
- Between October 2021 to January 2022, 14% of patients from OC jails that had HCV RNA detected accepted navigation services (i.e. insurance verification, verification of disease, identification of medical home). Fig 6.

Fig. 6 - Jail HCV RNA Results and Navigation Services October 2021-January 2022 n = 265



CONCLUSIONS/DISCUSSION

- HCV RNA assay verification was successful, as was the serum stability study to assess whether blood samples could be centrifuged >6-hours after collection.
- OCPHL had delays for HCV RNA test results to be transmitted through the LIS to OC Jails, but this issue was resolved, and testing is now ongoing using state HCV grant funds.
- OCPHL reflexed HCV Antibody equivocal specimens to HCV RNA since a low reactive result could signify someone who is in the early stages of seroconverting and obtaining another sample may not be possible.
- Due to assay stability limitations, HCV RNA specimens are batched weekly.
- Jails will continue to monitor how many patients are provided navigation services, how many receive treatment, and how many complete treatment.

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