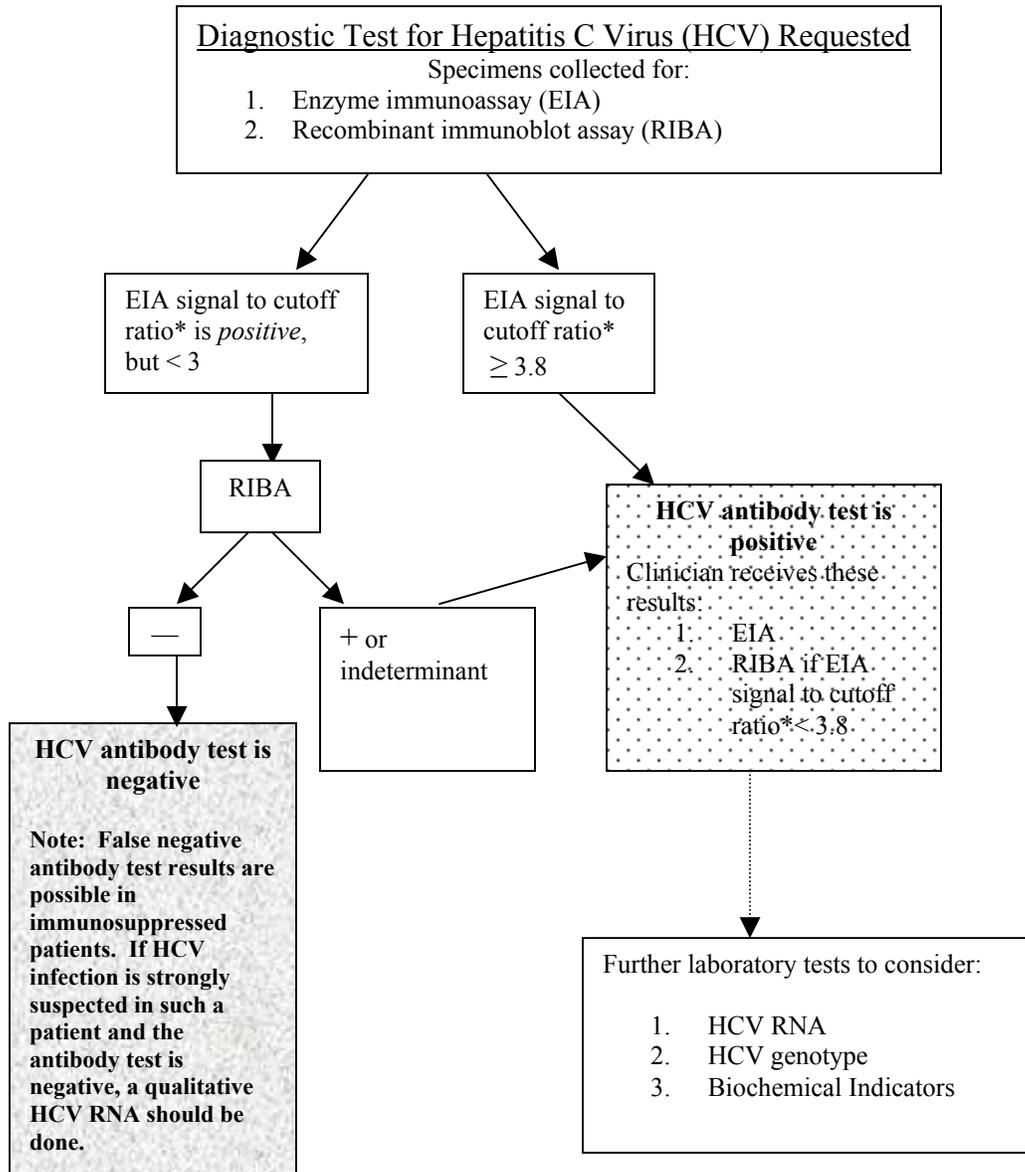


ATTACHMENT A

DIAGNOSTIC TESTING ALGORITHM #1



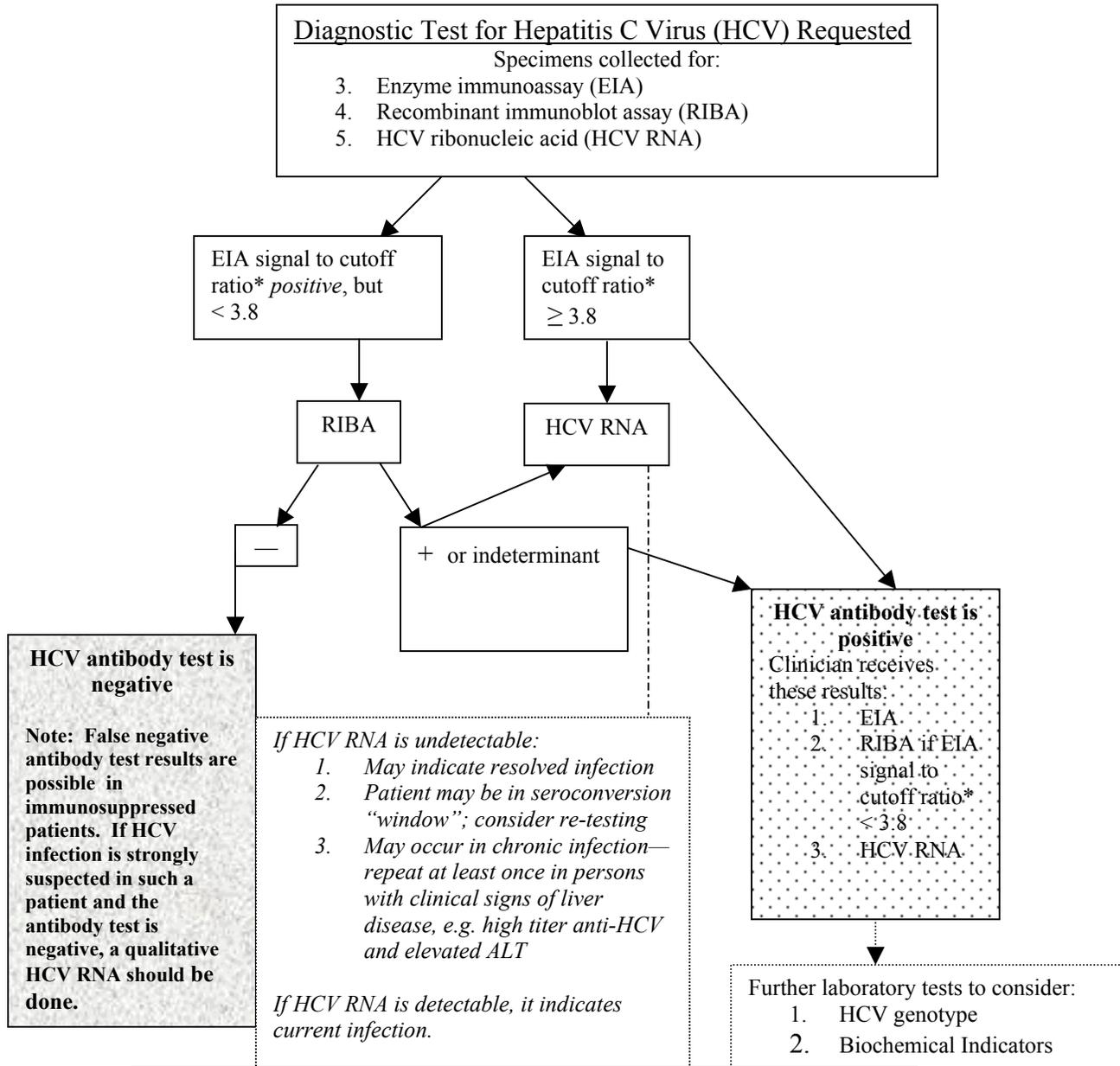
Summary of Algorithm #1 Outcomes:

1. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA negative → HCV antibody negative
2. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA positive → HCV antibody positive
3. EIA signal to cutoff ratio* ≥ 3.8 → HCV antibody positive

Note: Ascertainment of resolved vs. chronic infection requires HCV RNA.
Note: Development of a plan of care for chronic infection requires biochemical indicators, HCV genotype, and other clinical assessments.

*The 3.8 value should only be used with Ortho 3.0 or Abbott 3.0 assays.

DIAGNOSTIC TESTING ALGORITHM #2



Summary of Algorithm #2 Outcomes:

1. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA negative→HCV antibody negative
2. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA positive, HCV RNA negative→resolved HCV infection (likely)
3. EIA signal to cutoff ratio* *positive*, but < 3.8, RIBA pos, HCV RNA positive→chronic HCV infection
4. EIA signal to cutoff ratio* ≥ 3.8, HCV RNA negative→resolved HCV infection or seroconversion “window”, or chronic HCV with fluctuating viral load
5. EIA signal to cutoff ratio* ≥ 3.8, HCV RNA positive→chronic HCV infection

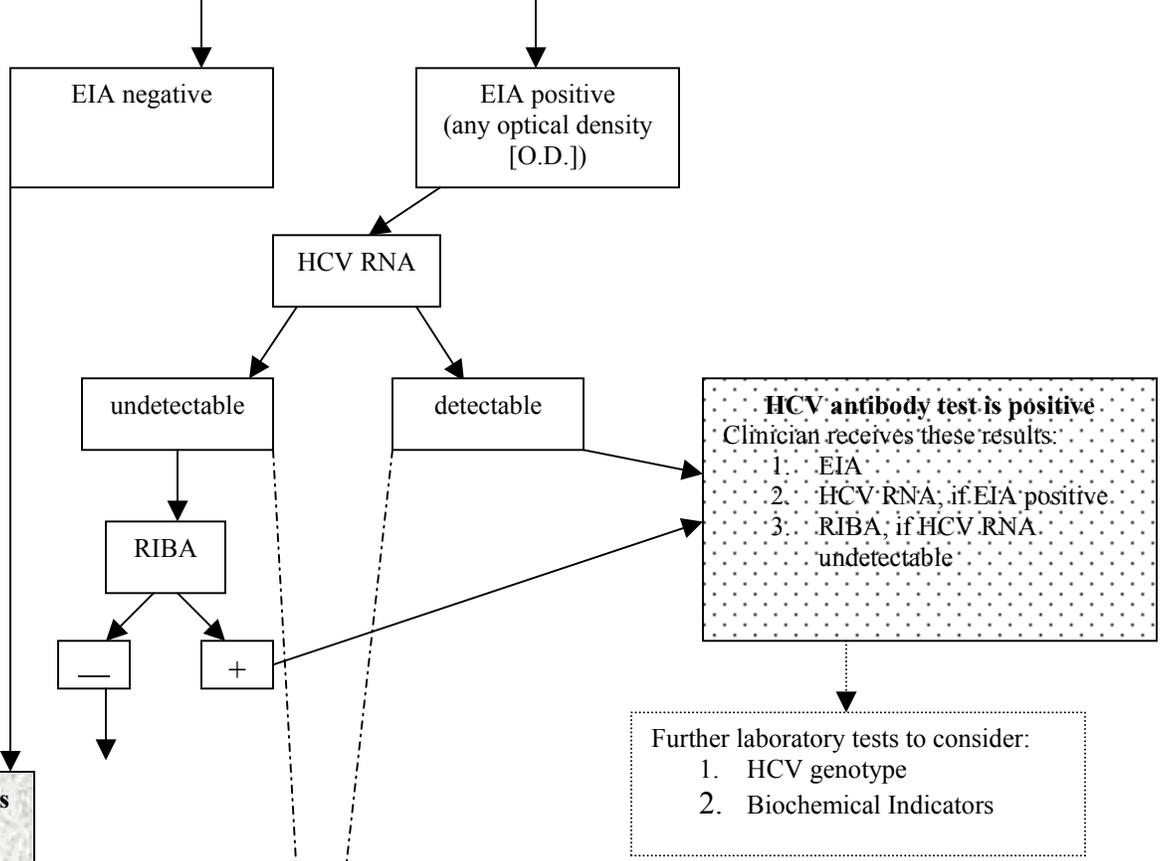
Note: Ascertainment of resolved vs. chronic infection requires HCV RNA.
 Note: Development of a plan of care for chronic infection requires biochemical indicators, HCV genotype, and other clinical assessments.

*The 3.8 value should only be used with Ortho 3.0 or Abbott 3.0 assays.

DIAGNOSTIC TESTING ALGORITHM #3

Diagnostic Test for Hepatitis C Virus (HCV) Requested
Specimens collected for:

1. Enzyme immunoassay (EIA)
2. Recombinant immunoblot assay (RIBA)
3. HCV ribonucleic acid (HCV RNA)



HCV antibody test is negative

Note: False negative antibody test results are possible in immunosuppressed patients. If HCV infection is strongly suspected in such a patient and the antibody test is negative, a qualitative HCV RNA should be done.

If HCV RNA is undetectable:

1. May indicate resolved infection
2. Patient may be in seroconversion "window"; consider re-testing
3. May occur in chronic infection—repeat at least once in persons with clinical signs of liver disease, e.g. high titer anti-HCV and elevated ALT

If HCV RNA is detectable, it indicates current infection.

Summary of Algorithm #3 Outcomes:

1. EIA negative→HCV antibody negative
2. EIA positive at any O.D, HCV RNA undetectable, RIBA negative→false positive EIA
3. EIA positive at any O.D, HCV RNA undetectable, RIBA positive→ resolved HCV infection or seroconversion "window", or chronic HCV w/fluctuating viral load
4. EIA positive at any O.D, HCV RNA detectable→chronic HCV infection

Note: Ascertainment of resolved vs. chronic infection requires HCV RNA.
Note: Development of a plan of care for chronic infection requires biochemical indicators, HCV genotype, and other clinical assessments.