

HCV Genotyping

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HCV Genotyping Assays

- Commercial Use:
 - Laboratory developed tests
 - INNO-LiPA HCV II (Innogenetics)
 - Trugene HCV (Siemens)
 - Linear Assay HCV Genotyping test (Roche Molecular)
- RUO
 - Real Time HCV Genotype II (Abbott)
- Developed during different treatment paradigm time periods
- No Standardization of samples explored
- In Development
 - Cobas HCV genotyping product (Roche Molecular)

Proposal for Comparison Data

- To assess performance of the various tests : standardized panels of HCV genotypes 1-6 should be explored
 - Establish a type of ‘proficiency testing’
 - Ensure sufficient ‘n’ to be relevant globally
 - Comparator to sequencing for discordant calls (gold standard)

Sources for Materials

- Commercial vendors
 - NIBSC
 - Acrometrix
 - Seracare

Set up larger panel manufacture?
- Pharma companies
 - When enrolling Phase III studies on a global basis, patients with 'unsuitable' genotypes are turned away
 - Parallel collection protocols to source 10-15 ml of plasma of endemic genotype samples?

Standardized Comparison-The Ideal

- Data should be presented with standardized panels
 - Contain at least 15-20 of each genotype 1a, 1b, 2, 3, 4, 5 and 6
 - Further support with data from test verification protocols (TPV studies used for CE registration)
 - Compare test A, test B to sequencing

Current Need:

Clinical Practice vs. Clinical Trials

- Clinical Practice:
 - Identification of patients suitable for triple therapy with a protease inhibitor: gt1 or non-gt1
- Clinical Trials:
 - Data capture of patient population
 - Expansion of DAAs to non-1 gt
 - Rapid evolving field in patient treatment
 - Significance of genotyping is changing
 - What will be needed by 2014 and forward?

Thank You

- Further Ideas for Discussion