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Title

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Authors

Martin, Nolan R.
Woelkers, Megan
Palacio, Megan
[et al.](#)

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Comparison of Gen5 and Gen6 High-Sensitivity Cardiac Troponin T in a Real-World Setting

Nolan R. Martin MD¹, Megan Woelkers², Megan Palacio PhD³, Raymond T. Suhandynata PhD³, Robert L. Fitzgerald PhD³, Lori B. Daniels MD, MAS²

¹Department of Medicine, University of California San Diego, La Jolla, CA

²Division of Cardiovascular Medicine, Department of Medicine, University of California San Diego, La Jolla, CA

³Department of Pathology, University of California San Diego, La Jolla, CA

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Introduction

- Accuracy and precision are crucial characteristics of high-sensitivity cardiac troponin T (hs-cTnT) assays
- Results are instrumental in managing patients in acute care settings
- Comparative analysis is necessary in anticipation of the transition to Gen6 hs-cTnT assays from Gen5
- **Study aim: Compare discordant Gen5 and Gen6 hs-cTnT results between same-sample assays in a real-world setting**

Methods

Retrospective analysis of same-specimen Gen5 and Gen6 assay results from 1,847 encounters at a single center

Statistical analysis:

- Cases were classified by peak hs-cTnT (based on sex-specific 99th percentile upper reference limit [URL]) and time-to-peak hs-cTnT
- Cases with discordance in peak or time-to-peak hs-cTnT were categorized into four groups:
 - Gen5 normal/Gen6 positive
 - Gen5 positive/Gen6 normal
 - Concordant but Gen5 positive sooner
 - Concordant but Gen6 positive sooner

Clinical case review:

- Up to 10 cases with the greatest relative difference between Gen5 and Gen6 results in each category were independently adjudicated by two physicians
- If categories contained fewer than 10 cases, all discordant cases were reviewed
- Adjudicators had complete access to medical records and relied on clinical history and objective data including vital signs, exam, labs, and studies to evaluate
- Cases were categorized as evidencing higher sensitivity by either assay, or as false positive/negative results

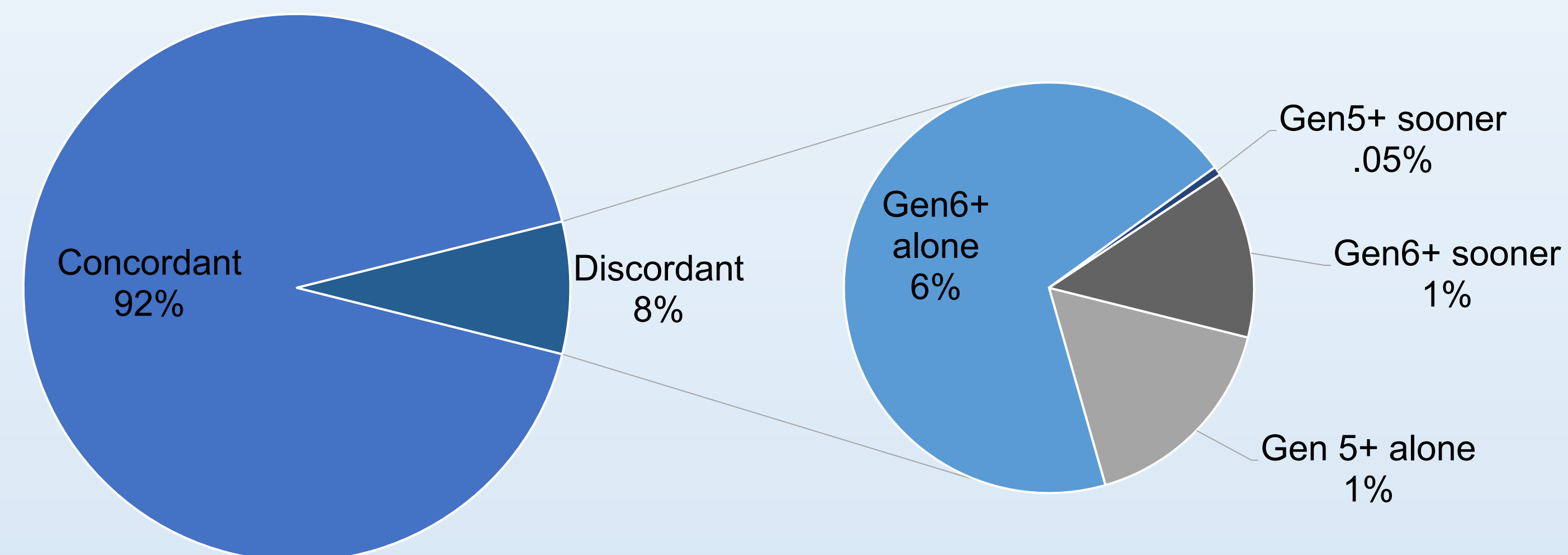


Figure 1. Overall Gen5/Gen6 concordance (1,847 encounters)

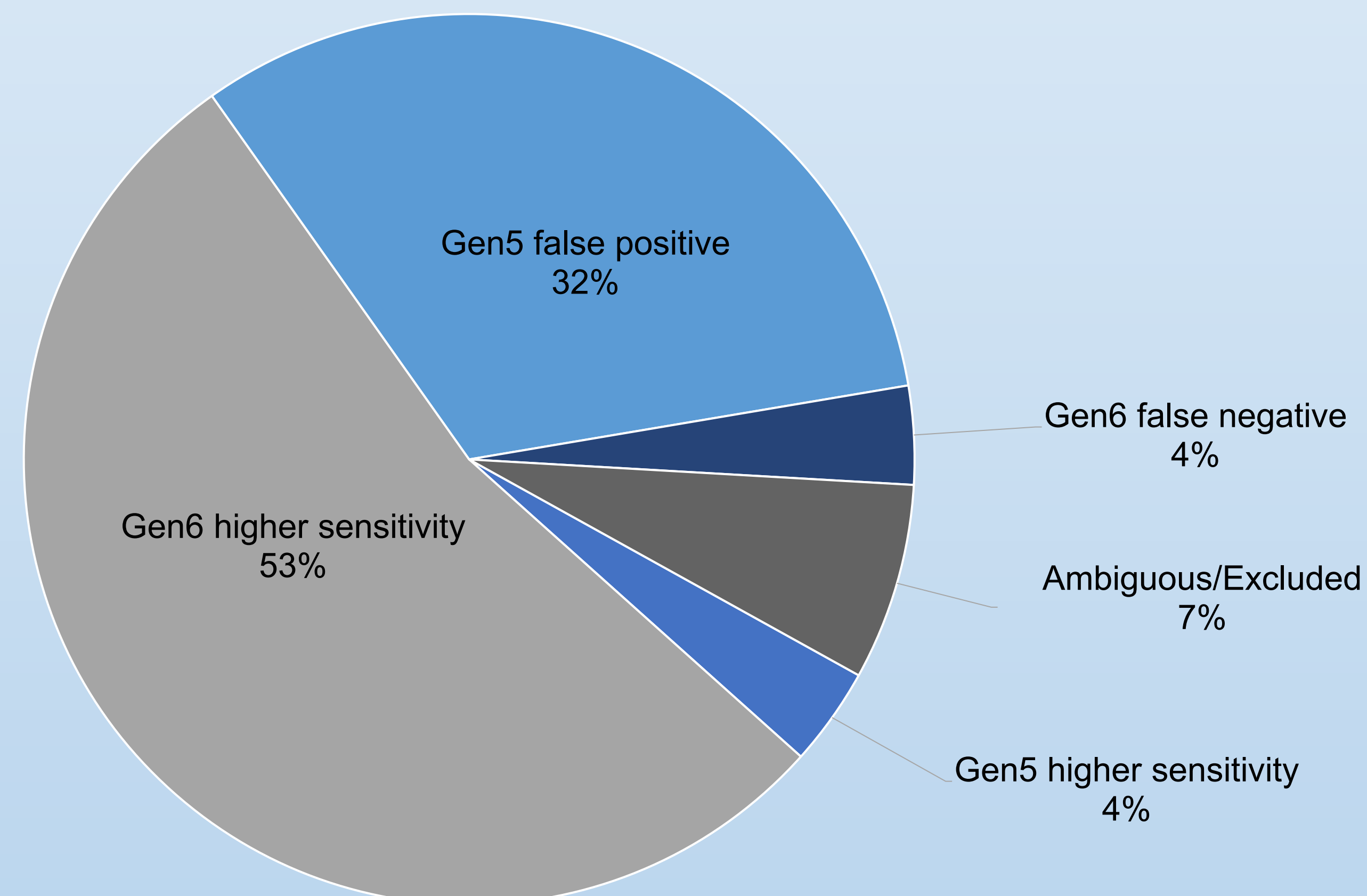


Figure 2. Categorization of adjudicated cases (28 encounters)

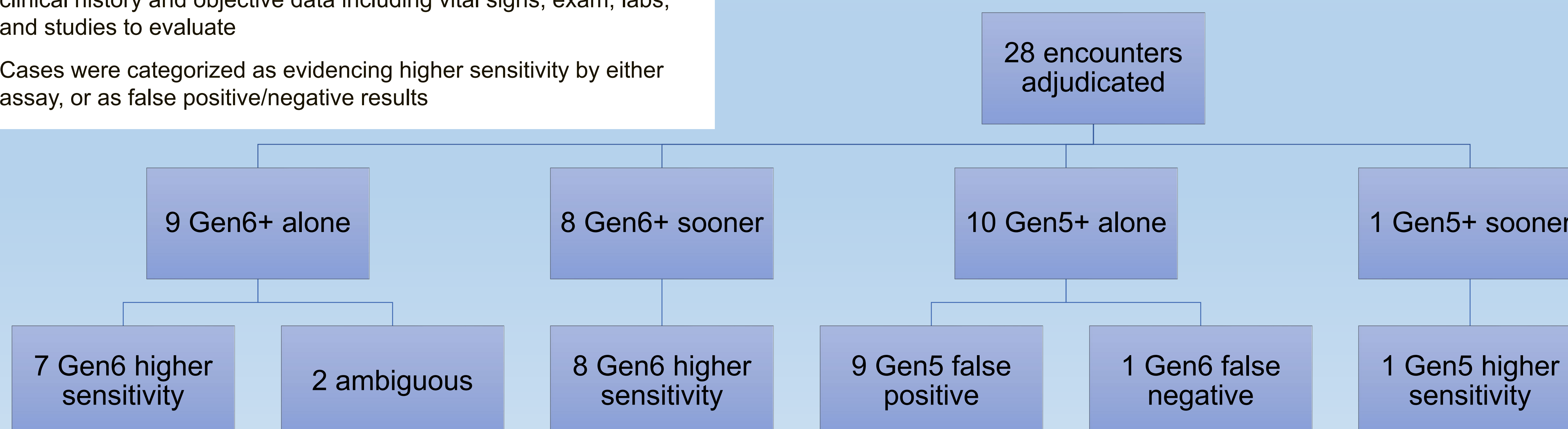


Figure 3. Flow of selected cases through adjudication

Results

Across all encounters (Figure 1):

- Hs-cTnT Gen5 and Gen6 were concordant in over 90% of cases (1,703 of 1,847 encounters, 92%)
- Gen6 was elevated alone in 5% (100 encounters) versus 1% (24 encounters) for Gen5
- Gen6 elevated sooner than Gen5 in 1% (19 cases) where both assays reached URL at different time points
- Conversely Gen5 rose sooner than Gen6 in only 1 case (0.05%)

Adjudicated encounters (Figures 2 and 3):

- 32 cases were selected for review
- Four cases were excluded for lack of complete records, leaving 28 encounters for adjudication
- Most discordant cases were shorter time-to-positive Gen6 (n=8, 29%) or Gen5-/Gen6+ (n=9, 32%)
- Four of the nine Gen5-/Gen6+ cases had a parallel trend in hs-cTnT for both assays, suggesting higher sensitivity for injury with Gen6
 - The remaining five Gen5-/Gen6+ cases included only single cTnT measurements
 - In 3 of these cases, Gen6 tracked with abnormal CK-MB, NT-proBNP, and symptoms, suggesting greater Gen6 sensitivity for myocardial injury
 - 2 of these cases were clinically ambiguous
- Of the 10 Gen5+/Gen6- cases, nine lacked signs or symptoms of ischemia and were ruled as Gen5 false positives
 - The remaining case exhibited a negative Gen6 result preceded by a positive Gen6 result, while Gen5 remained elevated, suggesting an isolated false negative Gen6 result
- The case in which Gen5 rose sooner than Gen6 showed similar trends between assays, but Gen5 had a faster time-to-positive and therefore was adjudicated as higher Gen 5 sensitivity

Conclusions

- In this single-center, real-world cohort of patients with hs-cTnT measured for routine care, Gen5 and Gen6 assays were concordant in most cases
- When assays diverged, Gen6 tended to show greater sensitivity for myocardial injury and fewer false positives compared to Gen5

Disclosure statement: the presenting author has no relationships to disclose.