



Use of Race in Prenatal Serum Screening

Draft Recommendation Evidence-to-Decision (EtD) Summary

RECOMMENDATIONS

RECOMMENDATION 1 (KQ3)

Laboratories should not include race-based adjustment factors or use race-specific medians when screening pregnant individuals for trisomy 21 (T21) risk assessment using human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A) during trimester 1. (Strength of Recommendation: Conditional; Certainty of Evidence: Low)

Summary Points:

- Few published studies were available for the panel to evaluate for KQ3, and the certainty of evidence was low.
- The evidence showed either no improvement or only modest improvement in screening performance.
- Using the EtD framework, the expert panel concluded that the harms of race-based adjustment moderately outweighed the benefits.
- **Together, the limited evidence, low certainty of evidence, and expert panel judgment informed Recommendation 1, indicating that the harms of race-based adjustment moderately outweighed the benefits.**

RECOMMENDATION 2 (KQ9)

Laboratories should not include race-based adjustment factors or use race-specific medians when screening pregnant individuals for T21 risk assessment using alpha fetoprotein (AFP), hCG, dimeric inhibin A (DIA), and unconjugated estriol (uE3) during trimester 2. (Strength of Recommendation: Conditional; Certainty of Evidence: Very Low)

Summary Points:

- Few published studies were available for the panel to evaluate for KQ9, and the certainty of evidence was very low.
- The evidence showed a modest improvement in screening performance when race-based adjustment factors were applied.
- Using the EtD framework, the expert panel concluded that the harms of race-based adjustment moderately outweighed the benefits.
- **Together, the limited evidence, very low certainty of evidence, and expert panel judgment informed Recommendation 2, indicating that the harms of race-based adjustment moderately outweighed the benefits.**

RECOMMENDATION 3 (KQ5)

Laboratories may include race-specific medians when screening pregnant individuals for open neural tube defects (ONTDs) using AFP during trimester 2.

Note: Defining race has important limitations. The data supporting this recommendation are based on few studies, and many populations are not represented.

(Strength of Recommendation: Conditional; Certainty of Evidence: Low)

Summary Points:

- Few published studies were available for the panel to evaluate for KQ5, and the certainty of evidence was low.

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The draft recommendations and supporting documents will be removed on July 16, 2026.

The draft recommendations along with the public comments received and completed evidence review will be reassessed by the expert panel in order to formulate the final recommendations.

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- Improved screening performance was noted across studies when race-based adjustment factors were applied.
- Using the EtD framework, the expert panel concluded that the benefit of improved ONTD screening outweighed the harms of race-based adjustment.
- **The consistent improvement in screening performance with race-based adjustment informed Recommendation 3. However, given the harms identified in the EtD, the expert panel emphasized in Good Practice Statements 1 and 2 that laboratories should use data from the populations they serve to determine whether race-based adjustment should be applied.**

GOOD PRACTICE STATEMENTS

GOOD PRACTICE STATEMENT 1

Laboratories should not include race-based adjustment factors or use race-based medians unsupported by evidence to improve screening outcomes.

GOOD PRACTICE STATEMENT 2

Laboratories should use medians that reflect the populations they serve rather than applying an adjustment factor relative to a single referent racial group.

Summary Points:

- The expert panel found limited, low-, or very low-certainty evidence to support the use of race-based adjustments across the key questions evaluated.
- Using the EtD framework, the expert panel concluded that there were significant harms associated with using a single race as an index population and applying an adjustment factor to other races to “correct” observed differences in biomarker concentrations.
- The expert panel concluded that race-based medians should not be used by default. Instead, laboratories should use evidence generated from the populations they serve to evaluate screening performance.
- The expert panel concluded that if race-based adjustments improve screening performance, the benefit of adjustment must be clearly weighed against the harms associated with race-based adjustment, as described in the EtD frameworks.

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