MAYO CLINIC

PROFICIENCY TESTING

MEASURING THE CLINICALLY RELEVANT RANGE OF VALUES

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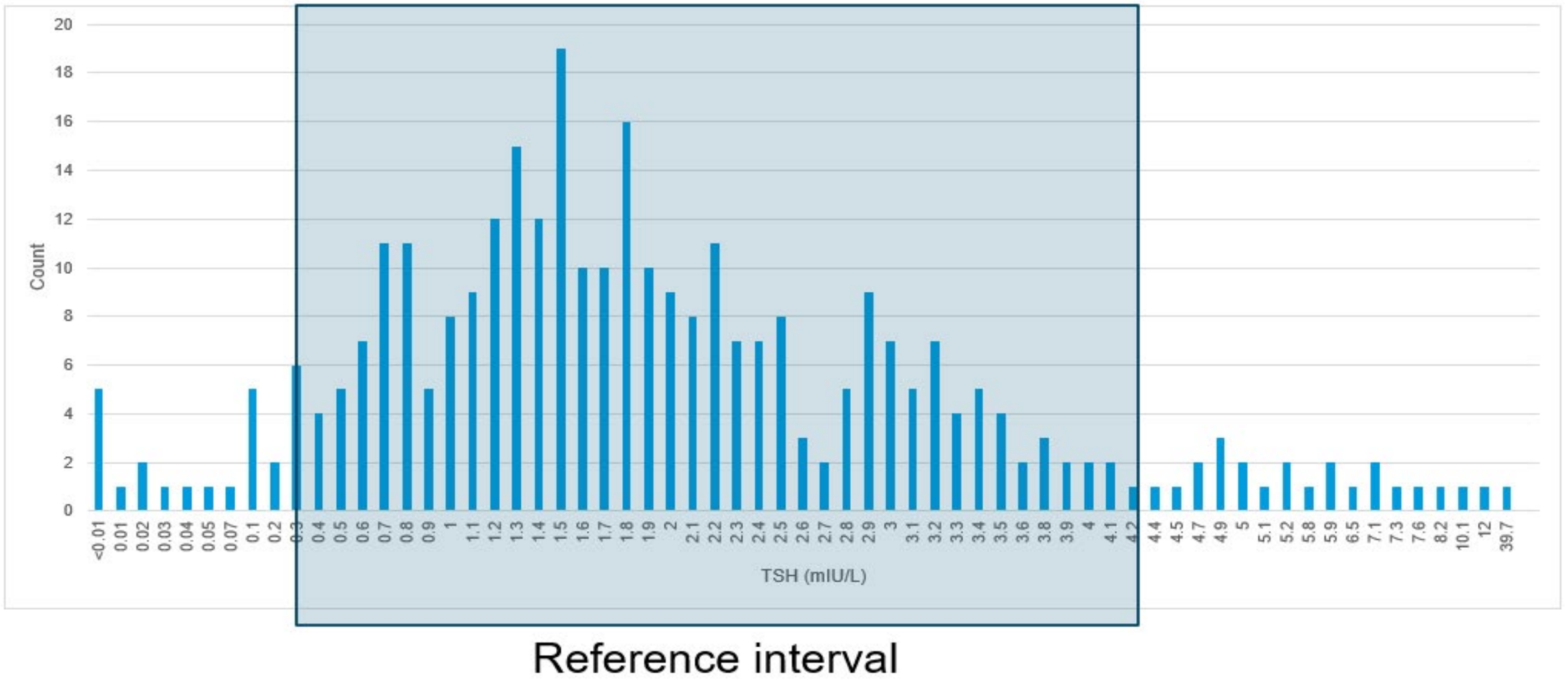
WHAT IS THE CLINICALLY RELEVANT RANGE OF VALUES FOR AN ASSAY?

Reference intervals	Interval of values observed in healthy subjects (central 95th %)

DISTRIBUTION OF THYROID STIMULATING HORMONE (TSH) RESULTS



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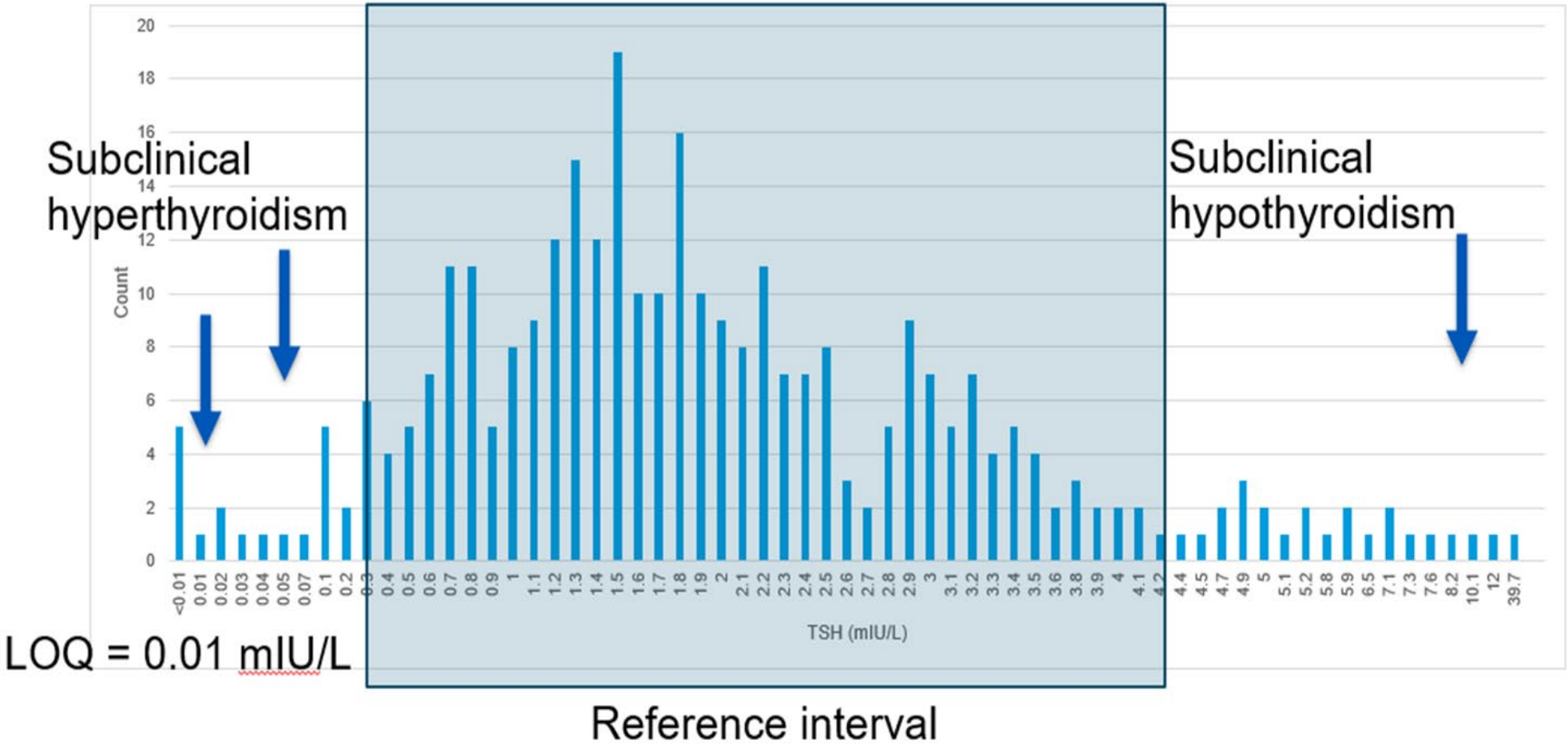

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Delta (change over time)	Reference change value Response to treatment

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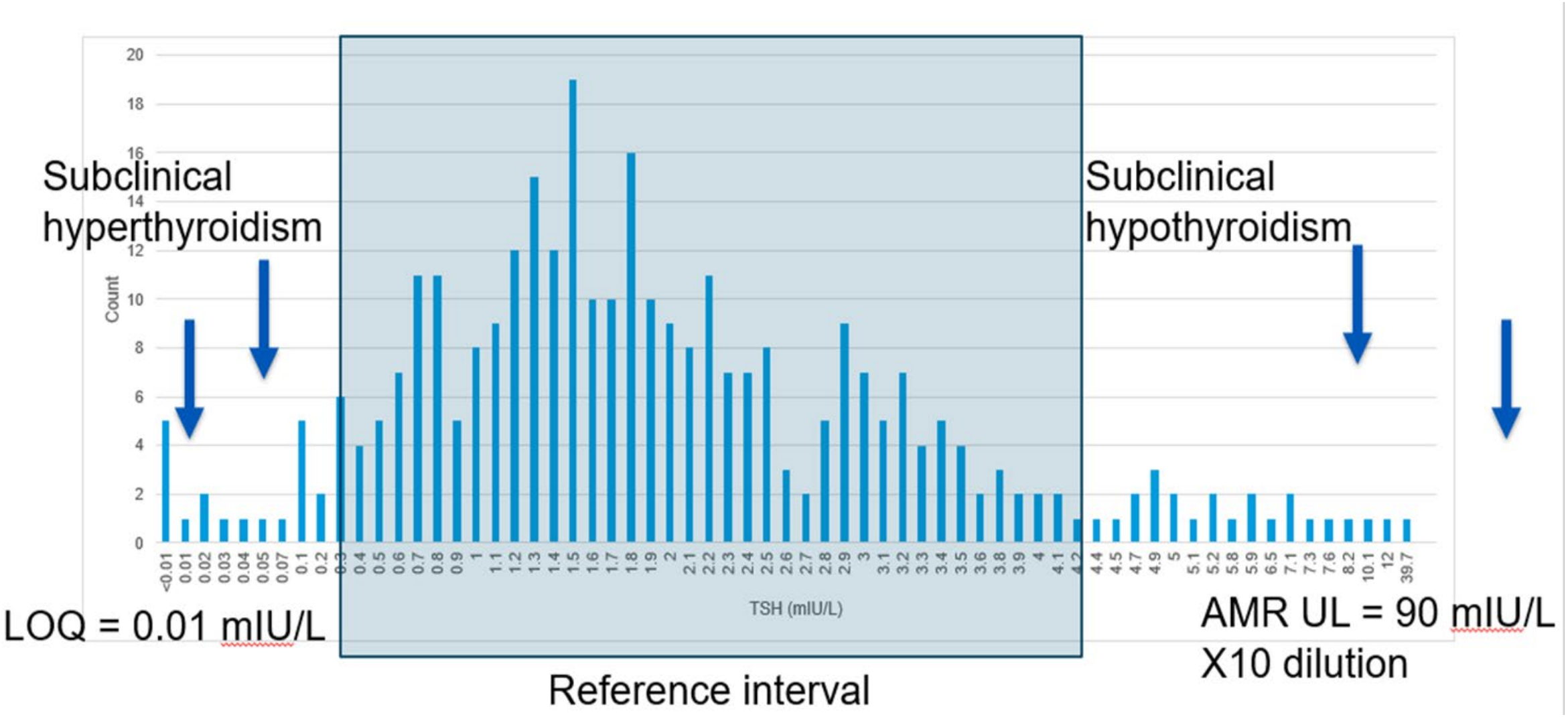
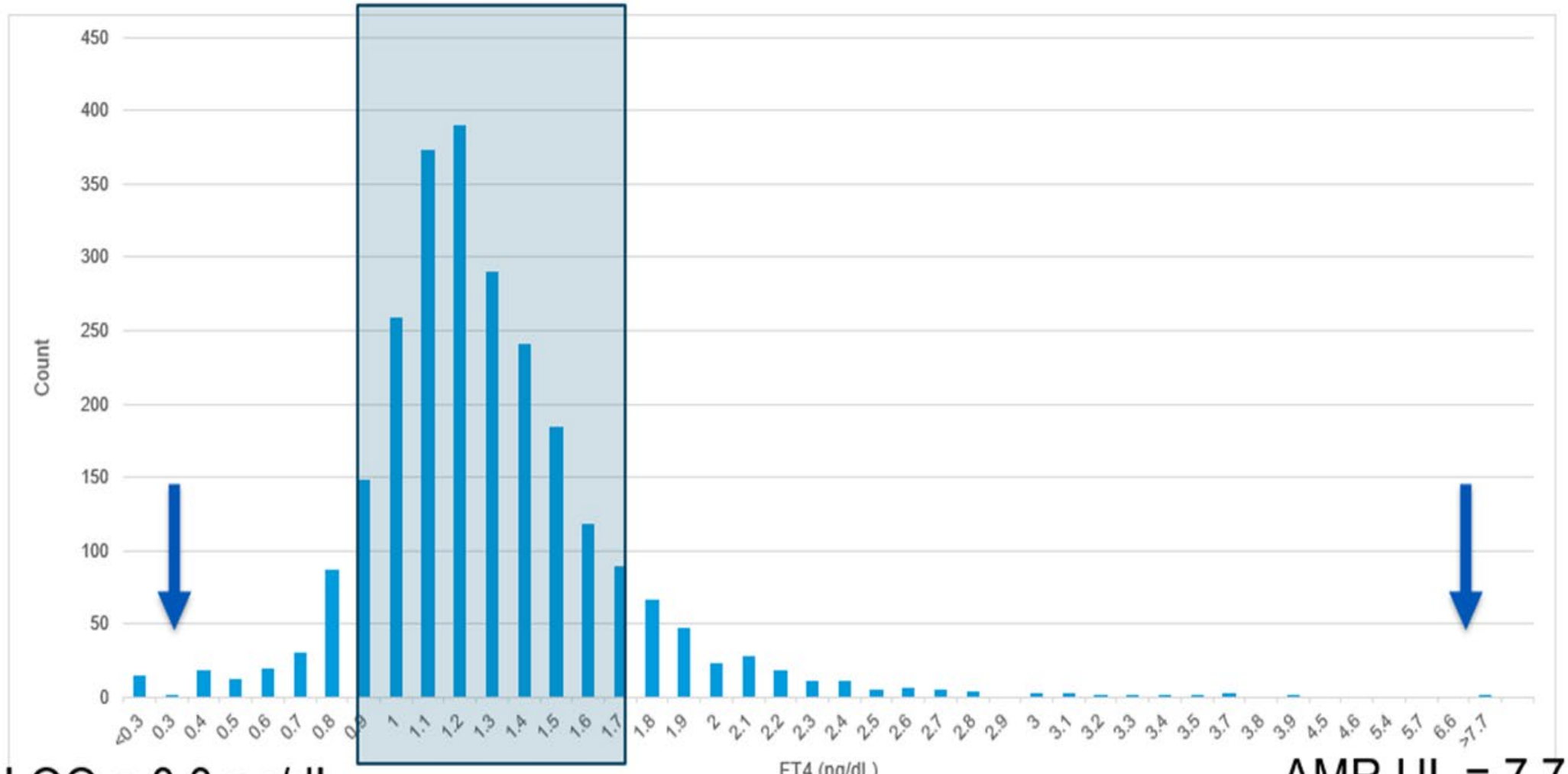


DISTRIBUTION OF FREE THYROXINE (FT4) RESULTS



LOQ = 0.3 ng/dL

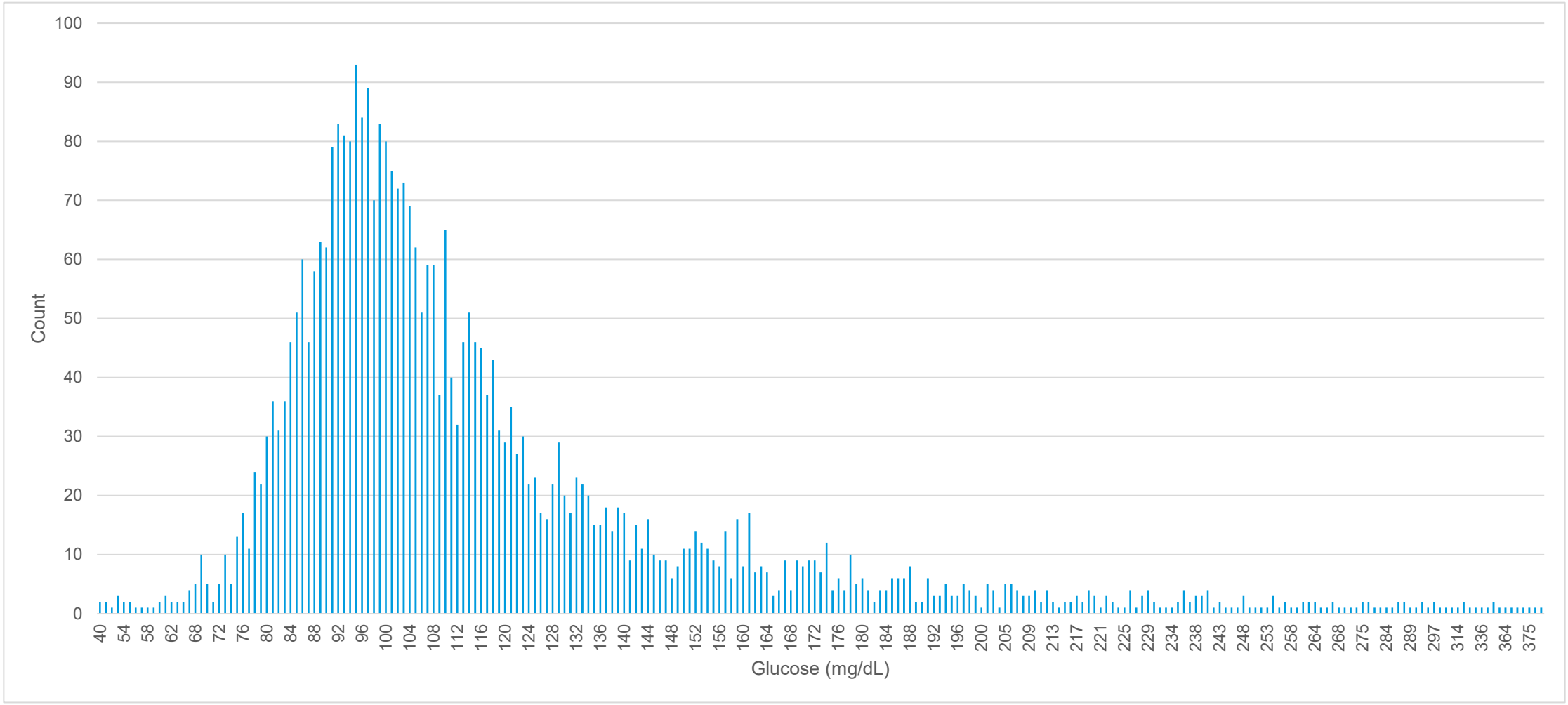
Reference Interval ~
Medical Decision Limit

AMR UL = 7.7 ng/dL
Critical value

WHAT IS THE CLINICALLY IRRELEVANT RANGE OF VALUES FOR AN ASSAY?

Physiologically improbable results within the AMR

DISTRIBUTION OF SERUM GLUCOSE RESULTS



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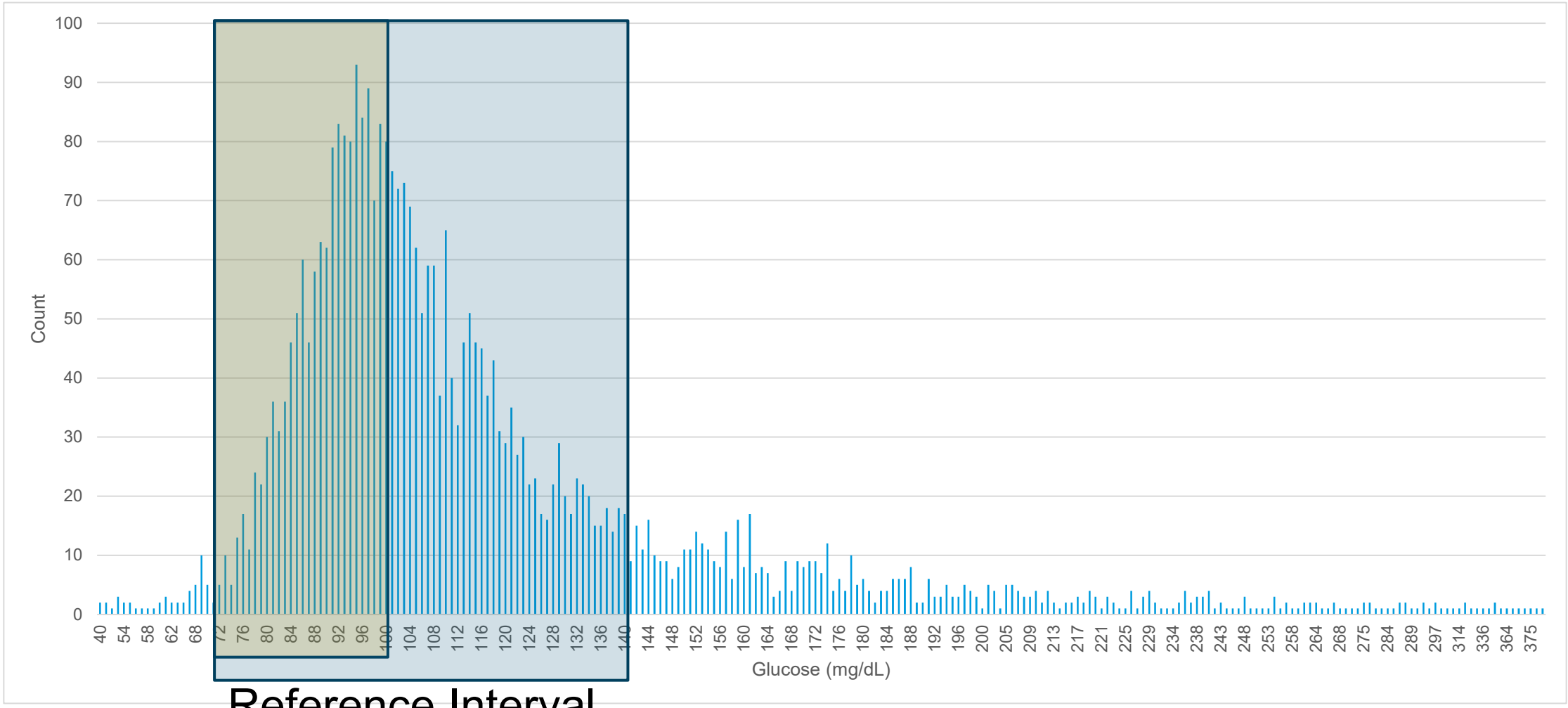

Reference Interval
Random 70-140 mg/dL
Fasting 70-100 mg/dL

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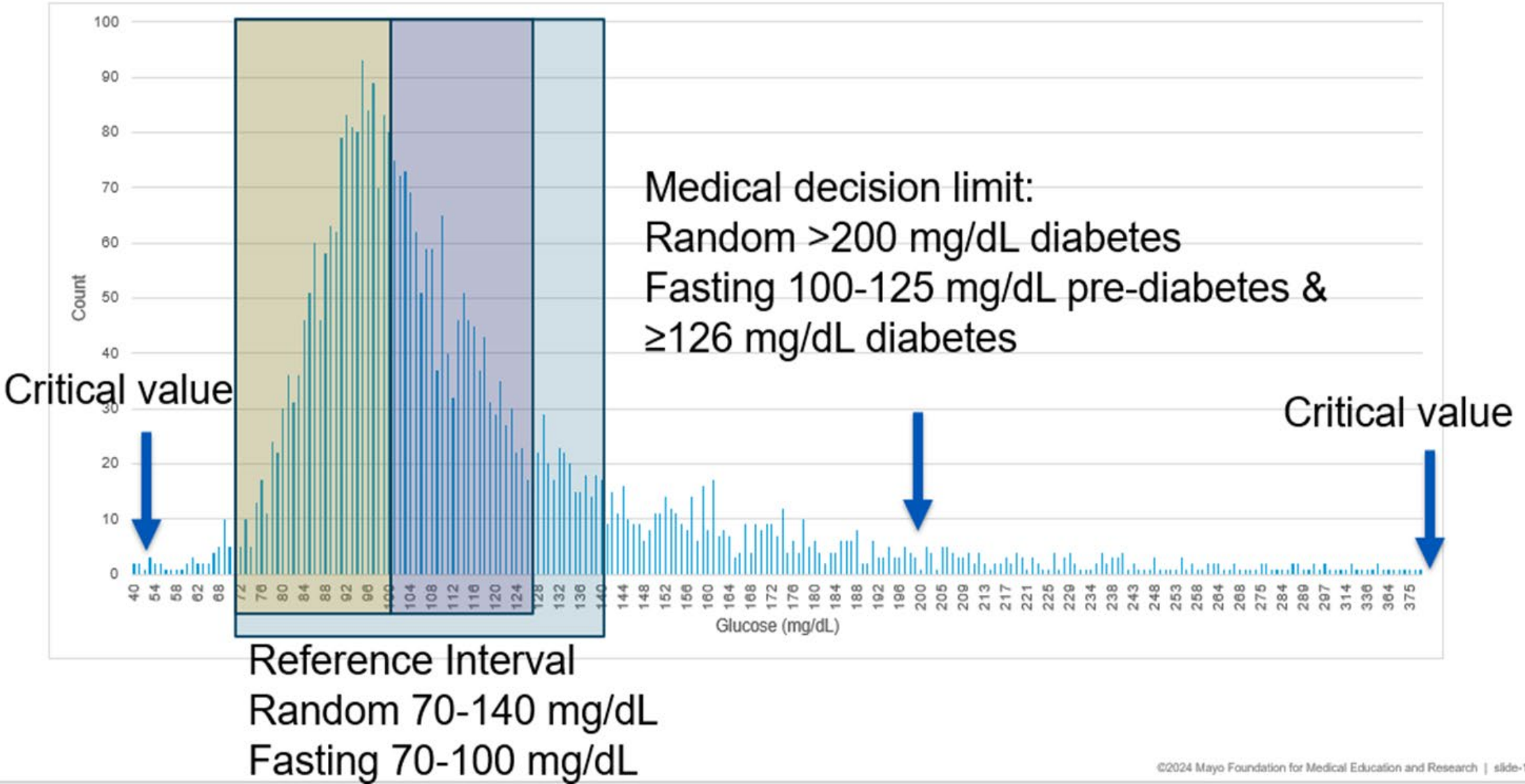

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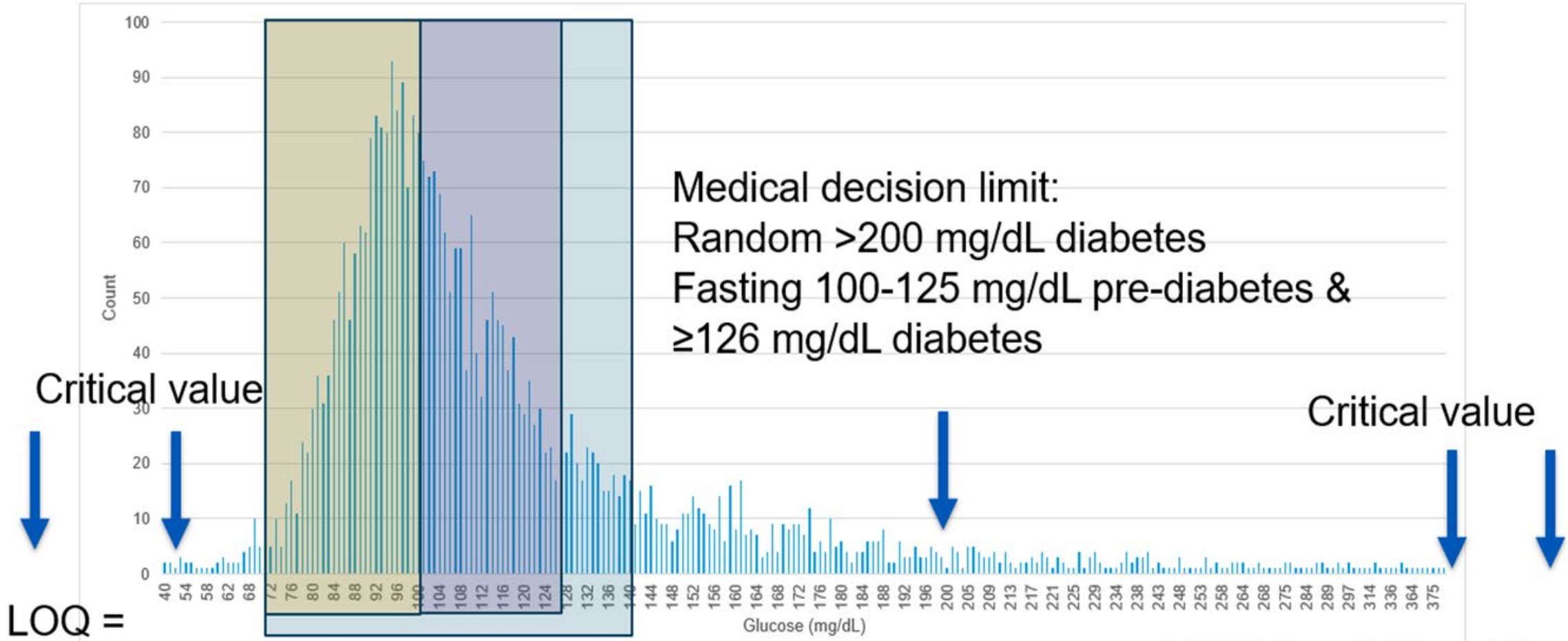

WHAT IS THE CLINICALLY IRRELEVANT RANGE OF VALUES FOR AN ASSAY?

Physiologically improbable results within the AMR:

Example: glucose between 2 mg/dL – 30 mg/dL

Extremes of measurement ranges

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Example: glucose between 2 mg/dL – 30 mg/dL

Extremes of measurement ranges

Caveat: Labs are accountable for accuracy within the AMR (independent of clinical relevance)

ACCOUNTABILITY: ANALYTICAL PERFORMANCE CHARACTERISTICS

Precision	Accuracy	Analytical measurement range	Reportable range	Reference intervals
• Reproducibility	• Truth	• Linearity • Recovery	• Dilution • Concentration	• Method • Population

CLINICALLY RELEVANT RANGE OF VALUES

Data-driven approach

Determine clinically irrelevant range of values

Considerations

- Reference intervals
- Medical decision limits
- Change in values over time

QUESTIONS & ANSWERS