



Pre-analytic Testing and Personnel Requirements



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Fundamental Question:

- Should CMS CLIA High Complexity Personnel Requirements apply to all aspects of a High Complexity test including Pre-analytic Testing?
 - Considerations in making this assessment:
 - Pre-analytic testing for some high complexity tests merely require instrument loading and many labs do not use HC Personnel for this function.
 - Should HC Personnel requirements apply to HC testing where there is no required manipulation or processing of the specimen beyond centrifuging and storage; there are no calculations or precision pipetting required.
 - No specimen rejection requirements that require individual assessment (i.e., hemolysis, clots, lipemia, blood to anticoagulant ratios, etc.)
 - Modular systems where modules can be taken off-line if quality issues are encountered