ANALYTICAL AND CLINICAL EVALUATION OF CARDIAC TROPONIN I AND ßhCG ON THE RADIOMETER AQT90 FLEX POC TESTING, RANDOM ACCESS ANALYZER

Betty J. Kilburn • Karen M. Schulz • MaryAnn M. Murakami • Fred S. Apple

Hennepin County Medical Center • Minneapolis, MN

Hennepin County Medical Center

ABSTRACT

The goal of this study was to evaluate the analytical performance of Radiometer's whole blood AQT90 Flex POC testing, random access analyzer for cardiac troponin I (cTnI) and beta hCG (βhCG). For cTnI the LoB, LoD, and LoQ were 0.0043 mg/L, 0.0095 mg/L, and 0.0095 mg/L, respectively. The linear range was 0 to 50 mg/L. Day to day imprecision (%CV) was 10% at 0.039 ug/L and 20% at 0.020 mg/L. 8% of the normal subjects (n=425 healthy blood donors) had a measurable concentration, with a 99th percentile value of 0.023 mg/L. There were no significant differences between whole blood and plasma, or between men and women. Correlation of 373 patient specimens with AQT cTnI concentrations < 5 mg/L between the AQT and the Siemens Stratus CS demonstrated the following regression: AQT cTnI = 0.258 Stratus CS + 0.001; r = 0.92. 382 patients that presented with symptoms suggestive of ACS , of which 85 (18.9%) had an MI, were evaluated. The ROC curve area under the curve for the baseline (0 to 2 hours after presentation) sample was 0.91. The clinical sensitivity and specificity using the 99th percentile value were 64.7% and 93.3%, respectively. For βhCG, the assay was linear between 2 to 5000 IU/L, with no hook effect up to 250,000 IU/L. No matrix effect was found between EDTA whole blood, EDTA plasma, Lithium heparin whole blood or Lithium heparin plasma. Based on 505 normal subjects, the reference intervals were: male (n=255) < 2 IU/L; female (n=250, all) <6 IU/L; postmenopausal (n=38) <6 IU/L; premenopausal (n=87) <2 IU/L. Imprecision (%CV) was 10 % at 8 IU/L. Correlation of 184 patient specimens with AQT90 ßhCG concentrations in the range of 2-5,000 IU/L (with the AQT90 FLEX ßhCG assay) demonstrated the following regression: AQT90 ßhCG = 1.291 Stratus CS - 7.2; r = 0.99. In conclusion, we have shown that the Radiometer AQT90 Flex random access analyzer provides diagnostically accurate rapid, whole blood, POC testing for both cTnI and βhCG, 2 critical tests that need to available in emergency settings on a 24/7 basis.

BACKGROUND

- In an emergency setting, a rapid accurate test for cardiac troponin I and ßhCG are very valuable in order to rapidly triage subjects.
- Radiometer (Copenhagen, Denmark) has developed a random access, whole blood, POC (point of care) analyzer called the AQT90 Flex analyzer.

PURPOSE

- The goal of this study was to evaluate the analytical performance of Radiometer's whole blood AQT90 Flex POC testing, random access analyzer for cardiac troponin I (cTnI) and beta hCG (ßhCG).

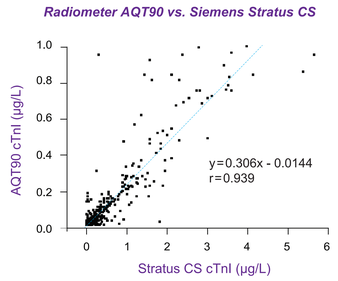
METHODS

- IRB approval obtained
- The evaluation of the AQT90 FLEX cTnI assay included CLSI-guided protocols to determine:
  - Limit of Blank (LoB) - determined from 60 measurements of the zero calibrator
  - Limit of Detection (LoD) - determined by measuring five low level cTnI pools in replicates of 5.
  - Limit of Quantitation (LoQ) - 10%CV - determined by measuring 10 low level cTnI pools in duplicate; twice a day for 10 days.
  - Reference Range Study - whole blood and plasma 99th percentile determined from blood collected from healthy volunteers with no history of heart disease.
  - Correlation Study - comparison of specimens assayed with the AQT90 cTnI assay and compared to results obtained using the Siemens Stratus CS cTnI from patients with symptoms suggestive of ACS.
  - Sensitivity & Specifity for MI diagnosis - were calculated based on final discharge diagnoses of 382 subjects presenting with symptoms of ACS based on baseline cTnI results.
- The AQT90 FLEX ßhCG evaluation included CLSI-guided protocols to determine:
  - Matrix Effect - evaluation of results obtained when blood is drawn into EDTA and LiHep anticoagulated blood collection tubes.
  - LoQ (10%CV) - determined by measuring 10 low level ßhCG pools in duplicate; twice a day for 10 days.
  - Normal Reference Range Study - whole blood and plasma normal reference range determined from 505 healthy volunteers.
  - Correlation Study - comparison of results from 184 specimens assayed with the AQT90 FLEX and Stratus CS ßhCG assays.

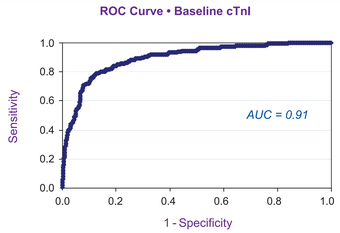
RESULTS • cTnI Assay

Linear Range	0-50 µg/L
Limit of Blank	0.0043 µg/L
Limit of Detection (µg/L)	0.0095 µg/L
Limit of Quantitation (µg/L)	0.0095 µg/L
10%CV	0.039 µg/L
99th Percentile (n=425)	0.023 µg/L

CORRELATION • cTnI



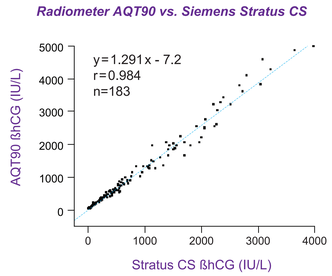
ROC CURVE • cTnI



RESULTS • ßhCG Assay

Linear Range		0-5000 IU/L
LoQ - 10%CV		8 IU/L
Reference Range • 95th percentile		
All	505	<2 IU/L
Men	255	<2 IU/L
Women	250	<6 IU/L
postmenopausal	38	<6 IU/L
premenopausal	87	<2 IU/L

CORRELATION • ßhCG



RESULTS

- The LoB, LoD, and LoQ for the AQT90 FLEX cTnI assay were 0.0043 µg/L, 0.0095 µg/L, and 0.039 µg/L, respectively.
- The AQT90 FLEX cTnI assay 99th percentile is 0.023µg/L determined from (n=425) healthy volunteers. 8% of the subjects had a measurable concentration. There were no significant differences between whole blood and plasma, or between men and women.
- The AQT09 FLEX cTnI assay day to day imprecision (%CV) was 10% at 0.039 ug/L and 20% at 0.020 µg/L.
- For the AQT90 FLEX ßhCG, the assay was linear between 2 to 5000 IU/L, with no hook effect up to 250,000 IU/L.
- No matrix effect was found between EDTA whole blood, EDTA plasma, Lithium heparin whole blood or Lithium heparin plasma using the AQT90 FLEX bhCG assay.
- Based on 505 normal subjects, the reference intervals for the AQT90 ßhCG were: male (n=255) < 2 IU/L; female (n=250, all) <6 IU/L; fpostmenopausal (n=38) <6 IU/L; premenopausal (n=87) <2 IU/L.
- Imprecision (%CV) was 10 % at 8 IU/L
- There was excellent correlation between the AQT90 and Stratus CS ßhCG assay (r=0.99).

CONCLUSIONS

We have shown that the Radiometer AQT90 FLEX random access analyzer provides diagnostically accurate, rapid, whole blood, POC testing for both cTnI and ßhCG; two critical tests that need to be available in emergency settings on a 24/7 basis.

Supported by Radiometer