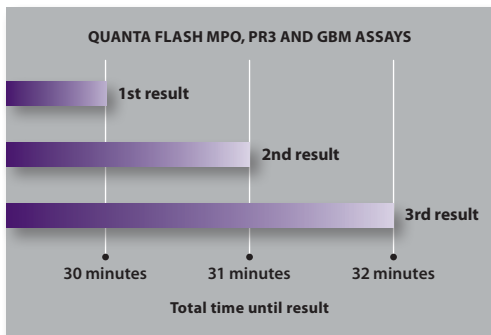


QUANTA Flash[®] Vasculitis



Responsive

QUANTA Flash MPO, PR3 and GBM allow for rapid response in critical cases



- A complete range of chemiluminescent assays to aid in differential diagnosis of ANCA-associated vasculitis and Goodpasture's syndrome
- Fully automated, random access processing with results in as little as 30 minutes
- Expanded dynamic range with excellent linearity provides confidence in follow-up testing¹

QUANTA Flash[®] Vasculitis

Clinical performance characteristics

Sensitive

- Chemiluminescent technology provides accurate autoantibody detection, even at low levels
- The highly purified native antigens allow for optimal performance
- QUANTA Flash PR3 has demonstrated correlation to disease activity for patients with granulomatosis with polyangiitis (n=46, p=.006)¹

Specific

- Assays display excellent specificity in differential diagnosis of critical disease states
- Assays perform well even with challenging disease cohorts (systemic lupus erythematosus, systemic sclerosis, rheumatoid arthritis)¹

Performance characteristics of QUANTA Flash vasculitis assays^{2,3}

| Reference # (50 tests/kit) | QUANTA Flash assay | Sensitivity (95% CI) | Specificity (95% CI) | Measuring range (CU) (Cut-off is 20) |
|-------------------------------|-----------------------|-------------------------|-------------------------|---|
| 701133 | MPO | 79.8% (69.9-87.6%) | 96.2% (94.2 - 97.6%) | 3.2-739.8 |
| 701138 | PR3 | 68.3% (58.3-77.2%) | 97.4% (95.8 - 98.6%) | 2.3-3285.3 |
| 701143 | GBM | 95.6% (89.0-98.8%) | 99.7% (98.6 - 100%) | 2.9-1437.8 |

QUANTA Flash vasculitis assays for use on the BIO-FLASH[®] rapid-response chemiluminescent analyzer

- Full-menu, random-access processing eliminates batching and allows for STAT testing
- On-board reagents and calibration curves make even the most specialized autoimmune tests efficient to perform
- Offers precise quantification and a broad dynamic range using chemiluminescent technology

References:

1. Mahler M, Radice A, Yang W, et al. Development and Performance Evaluation of Novel chemiluminescence Assays for Detection of Anti-PR3 and Anti-MPO Antibodies. *Clin. Chem. Acta.* 2012; 413:719-726.
2. Respective QUANTA Flash Product Directional Inserts.
3. Mahler M, Radice A, Sinico RA, et al. Performance evaluation of a novel chemiluminescence assay for detection of anti-GBM antibodies: an international multicenter study. *Nephrol Dial Transplant* 2011;1-10.

www.inovadx.com

San Diego, CA 92131 USA
PH: +1-858-586-9900 US Toll Free: 1-800-545-9495 FAX: +1-858-586-9911

BIO-FLASH is a registered trademark of biokit S.A. and QUANTA Flash is a registered trademark of Inova Diagnostics, Inc.
© 2014 Inova Diagnostics, Inc. All rights reserved.

690198 December 2014 Rev. 2

 **Inova
Diagnostics**
A Werfen Company