Technical Bulletin 135

MICROGEN BIOPRODUCTS

The New PathFlow™ Mononucleosis Rapid Test Cassette vs. a commonly used commercial kit, comparison analysis

Background of the 'Kissing Disease'

Infectious mononucleosis (IM, mono), also known as glandular fever, is an infection usually caused by the Epstein–Barr virus (EBV), also known as Human Herpesvirus 4. It is primarily spread through saliva but can rarely be spread through other bodily secretions. Most people are infected by the virus as children, when the disease produces few or no symptoms.

In young adults, the disease often results in fever, sore throat, enlarged lymph nodes in the neck, and tiredness. Most people recover in two to four weeks; however, feeling tired may last for months. The liver or spleen may also become swollen, and in less than one percent of cases splenic rupture may occur.

About 45 out of 100,000 people develop infectious mono each year in the United States[1]. Nearly 95% of people have had an EBV infection by the time they are adults[1]. The disease occurs equally at all times of the year[2].

Mono is primarily diagnosed based on the symptoms and can be confirmed with blood tests for specific antibodies. Another typical finding is increased blood lymphocytes of which more than 10% are atypical. **The monospot test is not recommended for general use due to poor accuracy[3].**

1. *Ebell, MH; Call, M; Shinholser, J; Gardner, J (12 April 2016). "Does This Patient Have Infectious Mononucleosis? The Rational Clinical Examination Systematic Review". JAMA. 315(14): 1502–9. doi:10.1001/jama.2016.2111. PMID 27115266.*
2. *Tyring, Stephen; Moore, Angela Yen; Lupi, Omar (2016). Mucocutaneous Manifestations of Viral Diseases: An Illustrated Guide to Diagnosis and Management (2 ed.). CRC Press.*
3. *"Epstein-Barr Virus and Infectious Mononucleosis Laboratory Testing". CDC. January 7, 2014. Archived from the original on 7 August 2016. Retrieved 10 August 2016.*

Evaluation

The New PathFlow™ Mononucleosis Rapid Test Cassette possesses a -Relative Accuracy- of 97.7%. The widely accepted commercial kit, reports a -Relative Accuracy- of 99.9%. Both tests were challenged using 9 positive and 9 negative external controls.

Results

Sample Identity	PathFlow™ M120CE	Commercial Kit	Comments
Mono Positive Control LOT: 1337F09P EXP: 2019-05-31	+	+	
Mono Positive Control LOT: 1337J11P EXP: 2019-08-31	+	+	
MONO Positive Control LOT: 17071143 EXP: 07-2019	+	+	
Status Mono Positive Control LOT: 15165 EXP: 05-2019	+	+	
NEQAS- LQ773117013	+	+	
NEQAS- LQ773117041	+	+	
NEQAS- LQ773117021	+	+	The **commercial kit** showed a **weak positive** reaction M120CE's reaction was conformant
Patient 180990977	+	+	
Patient 187088522	+	+	
MONO Negative Control LOT: 17071144 Exp: 2019-07	-	-	
MONO Negative Control LOT: 094701N EXP: 2019-04-30	-	-	
LQ773117043 (NEQAS)	-	-	
LQ773117011 (NEQAS)	-	-	
Patient 187090936	-	-	
Patient 187088166	-	-	
Patient 181020978	-	-	
Patient 184029901	-	-	
Patient 187090648	-	-	

Analysis

In general, rapid diagnostic kits are always likely to compromise sensitivity and specificity in the interest of speed, ease of use and cost. However, **PathFlow™ Mononucleosis Rapid Test Cassette** was developed having the patient's wellbeing as its pillar. Therefore, the product was only deemed adequate for customer use, when it achieved 97.7% of Relative Accuracy during its scalability process.

For maximum sensitivity at a minimum cost, **PathFlow™ Mononucleosis Rapid Test Cassette, should be your test of choice.**

Acknowledgements

Comparison study performed at Homerton University Hospital NHS Foundation Trust.

MICROGEN BIOPRODUCTS

Microgen Bioproducts Ltd, Unit 1, Watchmoor Point, Camberley, Surrey GU15 3AD, United Kingdom
T: +44 (0)1276 600 081 F: +44 (0)1276 600 151 E: enquiries.microgen@novacyt.com
www.microgenbioproducts.com

Doc. Reference: TB135, Revision -1
Date of Creation: January 2019
Template Reference: GTM003, Revision -1

CE

Part of the NOVACYT GROUP