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インフルエンザウイルスキット
『BD ベリター™ システム RSV』 ー 小児科領域における RS ウイルスの検出性能評価 ー
BD Veritor™ System RSV

2012 年 10 月に米国の ID WEEK™ におけるポスターセッション（Diagnostic Microbiology）で BD ベリター™ システム RSV の臨床評価の発表が行われました。その中で小児科領域における RS ウイルスの検出性能としてウイルス分離培養法及び RT-PCR との相関性試験の成績がまとめられましたのでお知らせいたします。

35581
ID WEEK
2012

Prospective, Multicenter, Clinical Evaluation of the BD Veritor™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) in Respiratory Specimens from Children

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ABSTRACT (Revised)

Background. An accurate point of care test for RSV detection is needed. We describe our experience with the BD Veritor™ System RSV test; a new-generation lateral flow immunochromatographic assay for objective-detection of RSV in respiratory specimens from children.

Methods. A prospective, multicenter clinical trial was undertaken to assess the performance of the BD Veritor™ System RSV test in comparison to both viral cell culture and PCR for RSV. Nasopharyngeal washes/aspirates (NPW/A) or nasopharyngeal swab (NPS) specimens from U.S. subjects ≤19 years of age were collected through prospective enrollment (2 sites) or salvage-specimen protocol (3 sites). All specimens were tested using the BD Veritor™ System RSV test within 72 hours of collection and inoculated into Diagnostic Hybrids R-Mix™ shell vials for RSV isolation. Frozen aliquots were batch tested utilizing the Prodesse™ ProFlu™+ RT-PCR assay.

Results. 1174 subjects were enrolled (median age <1 year) of which 1146 were study eligible. The performance of BD Veritor™ System RSV test compared to respiratory viral culture is summarized in Table 3. The BD Veritor™ RSV test invalid rate was low (1% for NPS; 2.3% for NPW/A). Analysis of the data indicates the sensitivity and specificity (all sample types combined) was 90% and 97.1% versus culture. The BD Veritor™ RSV test results were compared to RT-PCR for one of the five participating sites and gave 83.4% sensitivity and 97.5% specificity (Table 4).

Conclusions. Overall, the BD Veritor™ System RSV test performed well when compared to viral cell culture and PCR in children. The ease of use and the advantage of an objective read to eliminate subjectivity, make it an attractive point of care device for rapid RSV detection in respiratory specimens.

RESULTS

Table 3. Comparison of BD Veritor™ System for Rapid Detection of RSV versus Respiratory Viral Culture

Specimen Type	TP	FP	TN	FN	Total	% Sens. (95% CI)	% Spec. (95% CI)	% PPV (95% CI)	% NPV (95% CI)
NPS	153	9	524	20	706[a]	88.4 (82.8, 92.4)	98.3 (96.8, 99.2)	94.4 (90.2, 97.3)	96.3 (94.6, 97.6)
NPW/A	152	15	259	14	440[b]	91.6 (86.3, 94.9)	94.5 (91.2, 96.7)	91.0 (86.4, 94.6)	94.9 (92.0, 97.0)
Total	305	24	783	34	1146	90.0 (86.3, 92.7)	97.0 (95.6, 98.0)	92.7 (89.7, 95.1)	95.8 (94.4, 97.0)

Invalid Rates: [a]NPS = 1.0% (7/706); [b]NPW/A = 2.3% (10/440).

Table 4. Comparison of BD Veritor™ System for Rapid Detection of RSV versus RT-PCR[c]

Specimen Type	TP	FP	TN	FN	Total	% Sens. (95% CI)	% Spec. (95% CI)	% PPV (95% CI)	% NPV (95% CI)
NPS	95	2	207	27	331	77.9 (69.7, 84.4)	99.0 (96.4, 99.9)	97.9 (92.3, 99.9)	88.5 (83.7, 92.0)
NPW/A	116	6	110	15	247	88.5 (81.9, 93.0)	94.8 (88.9, 97.8)	95.1 (89.5, 97.9)	88.0 (81.0, 92.7)
Total	211	8	317	42	578	83.4 (78.3, 87.5)	97.5 (95.1, 98.8)	96.4 (92.8, 98.3)	88.3 (84.5, 91.3)

Invalid Rates: [c]PCR data from one site only

※ ABSTRACT 及び RESULTS は実際のポスター発表のスライドより抜粋

—ウイルス分離培養法との相関性—
本試験で採取された 1146 検体中、ウイルス分離培養法との比較では Nasopharyngeal Swab (NPS)及び Nasopharyngeal Washes / Aspirates (NPW/A)でそれぞれ 88.4%、91.6%の感度を示し、また 98.3%、94.5%の特異性が示されました。

—RT-PCR 法との相関性—
本試験で採取された 578 検体中、RT-PCR 法との比較では Nasopharyngeal Swab (NPS)及び Nasopharyngeal Washes / Aspirates (NPW/A)でそれぞれ 77.9%、88.5%の感度を示し、また 99.0%、94.8%の特異性が示されました。

※ Nasopharyngeal Swab は鼻腔ぬぐい液に相当します。
※ Nasopharyngeal Aspirates は鼻腔吸引液に相当します。
※ Nasopharyngeal Wash は鼻腔洗浄液（生食などで鼻腔内を洗浄する方法）に相当しますが、本邦では未承認の検体です。

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