1. Instruction for use for all the nine assays

RESPONSE: These have been provided to the reviewers.

2. The independent studies that provide analytical and clinical performance data in the IFU

RESPONSE: Individual papers demonstrating clinical utility of commercial Pneumocystis PCR tests, published as peer-reviewed articles

KitGENIE II Amplex


Evaluation of quantitative FTD-Pneumocystis jirovecii kit for Pneumocystis infection diagnosis.


Author information

Abstract

We evaluated the Fast track Diagnostics (FTD) Pneumocystis PCR kit, targeting the mitochondrial large subunit ribosomal RNA gene (mtLSU rRNA) of Pneumocystis jirovecii (P. jirovecii). A hundred and thirty-three patients were prospectively enrolled. Respiratory specimens were examined using both microscopy and the PCR assay. Twenty-six patients led to P. jirovecii detection. Fourteen patients presented with Pneumocystis pneumonia (PCP) whereas 12 patients were considered to be colonized. The median copy numbers in bronchoalveolar lavage fluid were significantly different in the PCP and colonization groups (1.35×10⁸/ml vs. 1.45×10⁵/ml, P < 0.0001). Lower and upper cut-off values of 3.9×10⁵ copies/ml and 3.2×10⁶ copies/ml allowed differentiating PCP and colonization. The FTD P. jirovecii assay was secondarily compared to an in-house reference PCR assay targeting the mtLSU rRNA gene. A concordance rate of 97.5% was observed (Cohen's kappa coefficient κ=0.935). The FTD Pneumocystis PCR kit showed good performance and represents an alternative method to diagnose P. jirovecii infections.

PMID: 28851493


Comparative Evaluation Between the RealStar Pneumocystis jirovecii PCR Kit
and the AmpliSens *Pneumocystis jirovecii* (carinii)-FRT PCR Kit for Detecting *P. jirovecii* in Non-HIV Immunocompromised Patients.

Huh H1, Lim KR2, Ki CS3, Shim HJ4, Song DJ1, Kim YJ5, Chung DR2,6, Lee NY7.

**Author information**

**Abstract**

**BACKGROUND:**

Real-time PCR is more sensitive than microscopic examination for detecting *Pneumocystis jirovecii*. We compared the performance of two assays for detecting *P. jirovecii* DNA: the RealStar *Pneumocystis jirovecii* PCR Kit 1.0 CE (Altona Diagnostics, Hamburg, Germany) and the AmpliSens *Pneumocystis jirovecii* (carinii)-FRT PCR kit (InterLabService Ltd., Moscow, Russia).

**METHODS:**

We used 159 samples from the lower respiratory tract (112 bronchoalveolar lavage [BAL] fluid, 37 sputum, and 10 endotracheal aspirate [ETA] samples) of non-HIV immunocompromised patients. Nested PCR and sequencing were used to resolve discordant results. The performance of the two assays was evaluated according to clinical categories (clinical *Pneumocystis* pneumonia [PCP], possible PCP, or unlikely PCP) based on clinical and radiological observations.

**RESULTS:**

The positive and negative percent agreement values were 100% (95% confidence interval [CI], 85.4-100%) and 96.6% (95% CI, 90.9-98.9%), respectively, and kappa was 0.92 (95% CI, 0.84-0.99). *P. jirovecii* DNA load was significantly higher in the clinical PCP group than in the other groups (*P*<0.05). When stratified by sample type, the positive rate for BAL fluids from the clinical PCP group was 100% using either assay, whereas the positive rate for sputum/ETA samples was only 20%.

**CONCLUSIONS:**

The two assays showed similar diagnostic performance and detected low *P. jirovecii* burden in BAL fluids. Both assays may be useful as routine methods for detecting *P. jirovecii* DNA in a clinical laboratory setting, though their results should be interpreted considering sample type.

PMID: 30430780


**Evaluation of a new commercial real-time PCR assay for diagnosis of**
Pneumocystis jirovecii pneumonia and identification of dihydropteroate synthase (DHPS) mutations.

Montesinos I1, Delforge ML2, Ajjaham F3, Brancart F4, Hites M5, Jacobs F6, Denis O7.

Author information

Abstract

The PneumoGenius® real-time PCR assay is a new commercial multiplex real-time PCR method, which detects the Pneumocystis mitochondrial ribosomal large subunit (mtLSU) and two dihydropteroate synthase (DHPS) point mutations. To evaluate the clinical performance of this new real-time PCR assay we tested 120 extracted DNA samples from bronchoalveolar lavage specimens. These set of extracted DNA samples had already tested positive for Pneumocystis and patients had been classified in probable and unlikely PCP in a previous study. To evaluate de accuracy of the DHPS mutant's identification, an "in house" PCR and sequencing was performed. The sensitivity and specificity of PneumoGenius® PCR in discriminating between probable and unlikely Pneumocystis pneumonia (PCP) were 70% and 82% respectively. PneumoGenius® PCR was able to genotype more samples than "in house" DHPS PCR and sequencing. The same DHPS mutations were observed by both methods in four patients: two patients with a single mutation in position 171 (Pro57Ser) and two patients with a double mutation in position 165 (Thr55Ala) and in position 171 (Pro57Ser). A low rate of P. jirovecii (4.5%) harboring DHPS mutations was found, comparable to rates observed in other European countries. The PneumoGenius® real-time PCR is a suitable real-time PCR for PCP diagnosis and detection of DHPS mutants. The added value of DHPS mutation identification can assist in understanding the role of these mutations in prophylaxis failure or treatment outcome.

PMID:27789058


Performances of Four Real-Time PCR Assays for Diagnosis of Pneumocystis jirovecii Pneumonia.

Sasso M1, Chastang-Dumas E1, Bastide S2, Alonso S2, Lechiche C3, Bourgeois N4, Lachaud L5.

Author information

Abstract

Pneumonia due to Pneumocystis jirovecii (PCP) is a frequent infection among HIV-positive or other immunocompromised patients. In the past several years, PCR on pulmonary samples has become an essential element for the laboratory diagnosis of PCP. Nevertheless, very few comparative studies of available PCR assays have been published. In this work, we evaluated the concordance between four real-time PCR assays, including three commercial kits, AmpliSens, MycAssay, and Bio-Evolution PCR, and an in-house PCR (J. Fillaux et al. 2008, J Microbiol Methods 75:258-261, doi:http://dx.doi.org/10.1016/j.mimet.2008.06.009), on 148 pulmonary samples. The results showed
Concordance rates ranging from 81.6% to 96.6% (kappa, 0.64 to 0.93). Concordance was excellent between three assays: the in-house assay, AmpliSens, and the MycAssay PCR (kappa, >0.8). The performances of these PCR assays were also evaluated according to the classification of the probability of PCP (proven, probable, possible, or no final diagnosis of PCP) based on clinical and radiological signs as well as the direct examination of bronchoalveolar lavage samples. In the proven PCP category, Pneumocystis jirovecii DNA was detected with all four assays. In the probable PCP category, the in-house PCR, AmpliSens, and the MycAssay PCR were positive for all samples, while the Bio-Evolution PCR failed to detect Pneumocystis jirovecii DNA in two samples. In the possible PCP category, the percentage of positive samples according to PCR varied from 54.5% to 86.4%. Detection of colonized patients is discussed. Finally, among the four evaluated PCR assays, one was not suitable for colonization detection but showed good performance in the proven and probable PCP groups. For the three other assays, performances were excellent and allowed detection of a very low fungal burden.

PMID: 26719435  PMCID: PMC4767985  DOI: 10.1128/JCM.02876-15

Comparision of 2 real-time PCR assays for diagnosis of Pneumocystis jirovecii pneumonia in human immunodeficiency virus (HIV) and non-HIV immunocompromised patients.

Montesinos I\textsuperscript{1}, Brancart F\textsuperscript{2}, Schepers K\textsuperscript{3}, Jacobs F\textsuperscript{4}, Denis O\textsuperscript{5}, Delforge ML\textsuperscript{6}

Author information

Abstract

A total of 120 bronchoalveolar lavage specimens from HIV and non-HIV immunocompromised patients, positive for Pneumocystis jirovecii by an "in house" real-time polymerase chain reaction (PCR), were evaluated by the Bio-Evolution Pneumocystis real-time PCR, a commercial quantitative assay. Patients were classified in 2 categories based on clinical and radiological findings: definite and unlikely Pneumocystis pneumonia (PCP). For the "in house" PCR, cycle threshold 34 was established as cut-off value to discriminate definite PCP from unlikely PCP with 65% and 85% of sensitivity and specificity, respectively. For the Bio-Evolution quantitative PCR, a cut-off value of 2.8×10(5) copies/mL was defined with 72% and 82% of sensitivity and specificity, respectively. Overlapped zones of results for definite and unlikely PCP were observed. Quantitative PCR is probably a useful tool for PCP diagnosis. However, for optimal management of PCP in non-HIV immunocompromised patients, operational thresholds should be assessed according to underlying diseases and other clinical and radiological parameters.

PMID: 25801778  DOI: 10.1016/j.diagmicrobio.2015.03.006

Comparison of a commercial real-time PCR assay, RealCycler® PJIR kit, progenie molecular, to an in-house real-time PCR assay for the diagnosis of Pneumocystis jirovecii infections.

Guillaud-Saumur T\textsuperscript{1}, Nevez G\textsuperscript{2}, Bazire A\textsuperscript{3}, Virmaux M\textsuperscript{4}, Papon N\textsuperscript{5}, Le Gal S\textsuperscript{6}.

**Author information**

**Abstract**

We compared the RealCycler® PJIR kit (Progenie Molecular), available in Europe, to an in-house real-time PCR assay for the diagnosis of Pneumocystis jirovecii infections. Excellent agreement was found (concordance rate, 97.4%; Cohen's kappa, 0.918>0.8) showing that this commercial assay represents an alternative method for the diagnosis of P. jirovecii infections.

PMID: 28143789

3. **Pricing**
RESPONSE: Updated annex 1

Annex 1

Commercial products in the submitted test category (please refer to the guidance document for an example):

*Intended use statements should be inserted below the table for each mentioned test.*

<table>
<thead>
<tr>
<th>Diagnostic Test trade name</th>
<th>Manufacturer name</th>
<th>Instrument trade name</th>
<th>Test trade name</th>
<th>Specimen Type(s)</th>
<th>Clinical Sensitivity (With detection thresholds for quantitative tests)</th>
<th>Clinical Specificity (With detection thresholds for quantitative tests)</th>
<th>Other relevant performance characteristics (e.g. limit of detection, bias for quantitative tests)</th>
<th>Time to result (mins)</th>
<th>Test price range USD (specify geographical region)</th>
<th>Instrument price range USD (specify geographical region)</th>
<th>Regulator y status of available products</th>
<th>Globally Available?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test 1: Easyplex® Pneumocystis jirovecii</td>
<td>Amplex</td>
<td>No extraction required, pre-treatment reagent provided with kitGENIE®II Mk 2 device with eazyReport® software</td>
<td>Nucleic acid (LAMP)</td>
<td>BAL, BS, TS (no DNA extraction required)</td>
<td>Clinical sensitivity: 100%</td>
<td>Clinical specificity: 98.1%</td>
<td>Inhibition rate: 8.6% No DNA extraction required. Freeze-dried reagents, ease kit transport.</td>
<td>30</td>
<td>354 euro for 24 reactions</td>
<td>CE-IVD</td>
<td>Yes?</td>
<td></td>
</tr>
<tr>
<td>Test 2: RealStar® Pneumocystis jirovecii PCR Kit 1.0</td>
<td>Altona Diagnostics</td>
<td>Validated extraction on Roche MagnaPure 96 (Comparable extraction performance is likely on other Roche extraction MagnaPure 24/Compact or Manual HighPure Spin columns) QIAamp® DNA Mini Kit (QIAGEN) and QIAasymp® (QIAGEN) NucliSENS® easyMag® (bioMérieux) (likely transferable to EMag) m2000sp (Abbott)</td>
<td>Nucleic acid (qPCR)</td>
<td>Extracted DNA from respiratory tract, oral, or nasopharyngeal samples</td>
<td>Clinical Sensitivity: 100%, Analytical sensitivity 0.29 copies/μl [95% confidence interval (CI): 0.19 - 0.55 copies/μl]</td>
<td>Clinical specificity: 97%, Analytical specificity: No reported cross-reactivity</td>
<td>Provides quantification through standards, Linear range: 10^1 copies/μl to 10^8 copies/μl Simultaneous detection of internal control target.</td>
<td>120</td>
<td>£974 for 96 reactions</td>
<td>$15000 (RotorGene), $45000 (Roche Lightcycler 480)</td>
<td>CE-IVD</td>
<td>&quot;Products not licensed with Health Canada and not FDA cleared or approved. Kits not available in all countries.&quot;</td>
</tr>
<tr>
<td>Test 3: PneumoGenius</td>
<td>PathoNostics</td>
<td>Validated extraction on BioMerieux EasyMag (likely transferable to EMag) and Qiagen Qiamp DNA Minikit</td>
<td>Nucleic acid (qPCR)</td>
<td>Extracted DNA from BAL (validated)</td>
<td>Clinical sensitivity: 70%</td>
<td>Clinical specificity: 82%</td>
<td>Ability to detect mutations in DHPS genes possibly associated with resistance to sulfa based treatments for PCR (e.g. septrin/Dapsone): Simultaneous detection of internal control target.</td>
<td>210</td>
<td>$344 for 25 reactions</td>
<td>$12000 (Mic qPCR), $15000 (RotorGene), $45000 (Roche Lightcycler 480)</td>
<td>CE-IVD</td>
<td>Broad (&gt;42 countries), no North American distribution</td>
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<p>| Test 4: AmpliSens® Pneumocystis jirovecii-FRT | InterLabService Ltd. | Validated extraction on Roche MagNApure 96 (Comparable extraction performance is likely on other Roche extraction MagNApure 24/Compact or Manual HighPure Spin | Nucleic acid (qPCR) | Extracted DNA from clinical material (BAL, sputum, oropharyng) | Analytical sensitivity: 500 copies/ml | Clinical sensitivity: 100% | Qualitative detection. Simultaneous detection of internal control target. | 60 | $370 (60 tests) | $15000 (RotorGene) | CE-IVD | Broad (&gt;53 countries) |
| Test 5: RIDA®GENE Pneumocystis jirovecii | R-Biopharm AG | Validated extraction on Roche MagNApure compact (Comparable extraction performance is likely on other Roche extraction MagnaPure 96/24 or Manual HighPure Spin columns); Validated extraction on BioMerieux EasyMag (likely transferable to EMag) and Abbott M24. Suitable for use with: LightCycler® 2.0/480 (Roche), Mx3005P (Agilent), ABI7500 (AB), m2000rt (Abbott), CFX96 (Bio-Rad), SmartCycler® (Cepheid), Rotor-Gene Q (Qiagen) | Nucleic acid (qPCR) | Extracted DNA from BAL | Clinical sensitivity: 83.9%, Analytical sensitivity: ≥10 DNA copies/reaction | Clinical specificity: 100%, Analytical specificity: No reported cross-reactivity | Provides quantification through standards. Simultaneous detection of internal control target. | 60 minute s followin g DNA extracti on | $1200/£100 00 (100 reactionns) | $15000 (RotorGene), $45000 (Roche Lightcycle r 480) | CE-IVD | Worldwide network of &gt;120 distributors |
| Test 6:  | Pneumocystis jirovecii | Bio-Evolution | Validated extraction on Qiagen EZ1 DNA tissue and QIamp DNA mini kit (Comparable extraction performance is likely on other Qiagen extraction platforms). | Nucleic acid (qPCR) | Extracted DNA from BAL (validated) | Clinical sensitivity: 88%, Analytical sensitivity: 5 copies/ul | Clinical specificity: 100% | Quantification linearity: 10-1,000,000 copies/ul, PPV: 100%, NPV: 89%. | 80 minutes following DNA extraction | $400 (25 tests) | $15000 (RotorGene), $45000 (Roche Lightcycler 480) | CE-IVD Worldwide (available for export) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test 7:  | RealCycler PJR kit | Progenie Molecular | Validated extraction on BioMerieux EasyMag (likely transferable to EMag). | Nucleic acid (qPCR) | Extracted DNA from respiratory samples (ie BAL, sputum, biopsy) | Analytical sensitivity: 1000 copies/ul Clinical Sensitivity: 100% | Clinical Specificity: 100% | &lt;120 minutes including DNA extraction, 90 minutes for PCR only | XXX for 24 reactions | $12000 (Mic qPCR), $15000 (RotorGene) | CE-IVD Yes? |</p>
<table>
<thead>
<tr>
<th>Test</th>
<th>Name</th>
<th>Platform</th>
<th>Extraction Platforms</th>
<th>Kit Components</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Cost</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>PneumID</td>
<td>OLM Diagnostics</td>
<td>Likely applicable to most Extraction platforms. Suitable for real-time PCR instruments</td>
<td>Nucleic acid (multiplex qPCR)</td>
<td>Extracted DNA from respiratory samples</td>
<td>N/A</td>
<td>N/A</td>
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<td>Developed following the MIQE guidelines. Simultaneous detection of internal control target. Requires minimal processing (4 steps)</td>
<td>Within 45 minutes of DNA extraction</td>
<td>$738 (£500) for 50 reactions</td>
<td>See other estimates.</td>
<td>CE-IVD</td>
</tr>
<tr>
<td>9</td>
<td>FTD-Pneumocystis jirovecii kit</td>
<td>Fasttrack diagnostics</td>
<td>Validated extraction on BioMerieux EasyMag (likely transferable to EMag) and Versant KPCR Molecular system PCR platforms: QuantStudio 5, Applied Biosystems 7500, CFX96, LightCycler®480 and RotorGene 6000</td>
<td>Nucleic acid (RT-qPCR)</td>
<td>extracted nucleic acid from respiratory samples (throat/nasal swabs, bronchoalveolar lavage and sputum)</td>
<td>Analytical sensitivity: $10^3$ copies/ml</td>
<td>Analytical specificity: 100%</td>
<td>Clinical sensitivity: 100%</td>
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<td></td>
<td>T8-ISO (TwistDx) - $5500, Genie (Optigene) - $17000, Mic qPCR cycler (bms) - $12500, Franklin (Biomeme) - $6000, open qPCR (Chai Bio) - $6500, Freedom 16 (Ubiquitome) - $6500</td>
<td>T8-ISO (TwistDx) - $5500, Genie (Optigene) - $17000, Mic qPCR cycler (bms) - $12500, Franklin (Biomeme) - $6000, open qPCR (Chai Bio) - $6500, Freedom 16 (Ubiquitome) - $6500</td>
<td>T8-ISO, Franklin, Freedom 16 CE-IVD: Genie, Mic qPCR, open qPCR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- BAL: bronchoalveolar lavage, BS: bronchial secretion, TS: tracheal secretion
- *These are not validated for use with kits unless specified, but potentially compatible with optimization – see price range fields for details
- RUO: T8-ISO, Franklin, Freedom 16
- CE-IVD: Genie, Mic qPCR, open qPCR
Some costs have been converted to USD (from GBP or EUR) according to current exchange rates, and are exclusive of any regional taxes.

**Intended use statement for each test mentioned:**

Test 1: eazyplex® Pneumocystis jirovecii (Cat. No. 7626) is a qualitative in vitro diagnostic medical device for the detection of Pneumocystis jirovecii from bronchoalveolar lavage fluid (BAL), broncheal secretion (BS) or tracheal secretion (TS). The test can be performed at any time by qualified professional staff in a medical laboratory. The intended use includes: diagnosis (confirmatory assay to verify results of previous testing) and aid to diagnosis (providing additional information to assist in the determination or verification of a patient’s clinical status, test is not the sole determinant) of all kind of patients via testing bronchoalveolar lavage fluid (BAL), broncheal secretion (BS) or tracheal secretion (TS).

Test 2: RealCycler® PJIR is an in vitro diagnostic kit of reagents which allows real-time PCR qualitative detection of Pneumocystis jirovecii DNA in clinical samples. The system includes an internal control of amplification to prevent false negatives due to reaction inhibition.

Test 3: The intended use includes: diagnosis (confirmatory assay to verify results of previous testing) and aid to diagnosis (providing additional information to assist in the determination or verification of a patient’s clinical status, test is not the sole determinant) of all kind of patients via testing bronchoalveolar lavage fluid (BAL). It has the added ability to detect mutations in DHPS genes possibly associated with resistance to sulfa based treatments for PCR (e.g. septrin/Dapsone), which given the limitations associated with the culture of Pneumocystis is a particular benefit.

Test 4: AmpliSens® Pneumocystis jirovecii (carinii)-FRT PCR kit for qualitative detection of Pneumocystis jirovecii (carinii) DNA in the clinical material by the polymerase chain reaction (PCR) with real-time hybridization-fluorescence detection using validated instruments.

Test 5: For in vitro diagnostic use. RIDA®GENE Pneumocystis jirovecii is a real-time PCR for the direct qualitative and quantitative detection of Pneumocystis jirovecii from human BAL. It is intended to use as an aid in diagnosis for respiratory infections caused by Pneumocystis jirovecii.

Test 6: Pneumocystis jirovecii real time PCR kit is used for the quantitative or qualitative detection of bacterial DNA of Pneumocystis jirovecii in bronchoalveolar lavage by using real time PCR systems.

Test 7: RealCycler® PJIR is an in vitro diagnostic kit of reagents which allows real-time PCR qualitative detection of Pneumocystis jirovecii DNA in clinical samples. The system includes an internal control of amplification to prevent false negatives due to reaction inhibition.
Test 8: PneumID is a PCR kit for the detection of Pneumocystis jirovecii.

Test 9: FTD Pneumocystis jirovecii is an in vitro test for the quantitative detection of nucleic acid as an aid to the evaluation of infections with Pneumocystis jirovecii. The assay uses Equine arteritis virus (EAV) as an extraction control - the internal control (IC) - which is introduced by the laboratory into each sample and also in the negative control once the lysis buffer has been added during the extraction process.

**Extraction Platforms.**

The extraction of nucleic acid from respiratory samples for Pp PCR is a relatively straightforward procedure. Unlike, the detection of other fungal respiratory pathogens (e.g. *Aspergillus*) no specific methodological recommendations are required. Indeed, the nucleic acid extracts from samples that are sent in an attempt to diagnose respiratory viral infection can be used directly for Pp PCR. Consequently, Pp PCR can be performed in any centre that offers routine molecular diagnosis. A wide range of nucleic acid extraction platforms, both manual and automated have been used for Pp PCR, which is important in providing assay robustness, but also permit use in resource limited countries where the range of nucleic acid extraction platforms may be limited. Most PCR assays have been validated with multiple nucleic acid extraction platforms, usually involving both automated and manual methods, and combining a commercial PCR with a novel extraction method, only requires limited local validation, given external quality assessment schemes are available for Pp PCR. One assay, the easyplex® *Pneumocystis jirovecii*, can be performed without the need for nucleic acid extraction, reagents are lyophilized permitting shipment and storage at ambient temperatures, both advantageous in resource limited countries, albeit until clinical sensitivity is verified it would not be wise to use PCR negativity to exclude Pp. It also generates results within 30 minutes, which is useful for management of patients who do not regularly visit clinics. However, all methods can generate results within a 4 hours of sample receipt. To date, automated extractors from all the main molecular diagnostic companies (Abbott, Promega, Siemens, Qiagen, Roche and BioMerieux) have been successfully coupled with commercial PCR systems. The most widely used manual method (Qiagen Qiamp DNA minikit) has been used successfully. This provides access to a wide range of extraction methods to permit Pp PCR testing.

To avoid the reporting of false negative results it is essential that all internal controls are included to monitor for inhibition of the PCR process/efficiency of nucleic acid extraction and to determine quality of sampling and the influence of storage (e.g usually a Human gene target such as RNAse P, or β-Globin). The majority of the commercial assays utilize an internal control that is introduced prior to, or at an early stage of nucleic acid extraction, thus providing the optimal internal control process.
Real-time PCR platforms

With the exception of the Easyplex system, all commercial assays are validated for testing on a range of widely used real-time PCR platforms which provides robustness and broad applicability to existing molecular units, removing the need to purchase expensive individual equipment, and also provides continuity/familiarity for users, limiting the need for user familiarization with new software. Generally performance is comparable across platforms, with good to excellent concordance (>80% observed agreement) between results generated by the different assays. Pooled sensitivity and specificity for the commercial PCR assays listed above across nine independent studies (318 PcP cases and 919 No PcP controls) was 90.6% and 83.2%, respectively. Generating PPV, NPV, positive and negative likelihood ratios of 65.2%, 96.2%, 5.39 and 0.11, respectively, and a very good (discriminatory) diagnostic odds ratio of 49.