

# Performance of the IDEXX inVue Dx Cellular Analyser in Dogs and Cats with Clinical Otitis Externa

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## Background

External ear disease (otitis externa) is a common condition in dogs and cats that involves bacterial or yeast overgrowth (dysbiosis), infection, or otocariasis (ear mites).<sup>1-4</sup> Diagnosing ear disease in dogs and cats requires evaluating the complete clinical picture, including patient history, otoscopic examination, and ear cytology.<sup>4-6</sup> Cytology helps determine the presence and significance of bacterial or yeast populations within the ear, often representing dysbiosis or infection that perpetuates inflammation and the patient's ear disease. Thus, ear cytology is vital to appropriate management of otitis in dogs and cats.

However, conventional ear cytology remains a subjective method without standardised procedures for slide preparation or semiquantitative assessment, and clear criteria for differentiating true infection from bacterial overgrowth are lacking. Because the ear is a nonsterile environment, findings must be interpreted in the context of clinical signs. For instance, low numbers of organisms may reflect secondary overgrowth from conditions such as atopic dermatitis rather than infection requiring antimicrobial therapy.

The inherent limitations of conventional ear cytology are well described in veterinary dermatology studies. A recent study of two different ear swabs collected from the same ear revealed only moderate correlation between the specimens in the semiquantification of yeast and a high rate of discordance, 42%, for the assessment of the presence of rod-shaped bacteria (rods).<sup>7</sup> Another study of evaluators of ear and skin cytology specimens found interobserver agreement among board-certified dermatologists and residents identifying cocci-shaped bacteria (cocci) was only 64.6%, even when agreement was generously defined as within one grade on a 0-4+ scale.<sup>8</sup> In another veterinary dermatology study of bacterial folliculitis, three similarly experienced evaluators showed poor to moderate correlation in semiquantification of cocci by two different skin cytology methods and poor correlation for rod counts with both methods. The observers also demonstrated frequent intraobserver variation when reading the slides again after an unspecified wash-out period.<sup>9</sup>

While research involving expert evaluators of skin and ear cytology demonstrates notable subjectivity in conventional glass-slide microscopy, the accuracy of ear cytology assessment is potentially

compromised by additional factors. Inadequate collection of a representative cerumen sample from the ear, the presence of stain precipitates or contaminants within the Coplin staining jars during slide preparation, or improper fixation of cellular material can confound precise evaluation in routine ear cytology sample analysis. With all this variation that exists between slide assessment and between slides, plus the amount of time required to make, stain, dry, and read a slide, there is real benefit to having an automated system that evaluates patient ear samples the same way every time.

The IDEXX inVue Dx™ Cellular Analyser is such a system providing automated ear cytology in the veterinary clinic. The IDEXX inVue Dx analyser represents a paradigm shift in the assessment of ear cytology, providing a simple load-and-go strategy to evaluate ear samples. Analyser reagents come prepackaged, free of contamination with sterile reagents and stains. Ear swabs are mixed in a liquid diluent tube housing reagents that separate cerumen from other elements in the sample. Fluorescent stains in the reagents bind to yeast, bacteria, and white blood cells (WBCs). The fluid is dispensed into a sample cartridge and loaded into the analyser. The preparation takes only a minute and in 8 minutes the platform examines thousands of images under bright field and fluorescent light to locate and classify different elements of the sample. The IDEXX inVue Dx analyser assesses these multiple fields of view and fluid depths to identify WBCs, cocci-shaped bacteria (cocci), rod-shaped bacteria (rods), yeast, and mites. In doing so, the IDEXX inVue Dx analyser examines up to 10 times more of the sample than is practical in traditional ear slide reviews. Unlike traditional cytology, which relies on a limited subset of cells from a glass slide and is therefore prone to sampling error, the analyser examines a substantially larger portion of the sample, reducing variance and improving diagnostic accuracy through a larger evaluation of the available sample. In this way, the IDEXX inVue Dx analyser provides objective, standardised, semiquantification of bacteria and yeast to support clinical interpretation and trending of patient results. The IDEXX inVue Dx analyser assesses the presence or absence of WBCs and *Otodectes* mites. Plus, the automation of the IDEXX inVue Dx analyser platform allows veterinarians or nurses to perform other important duties during the analysis time rather than creating, staining, and reading traditional glass slide preparations.

## Study 1: Performance of the IDEXX inVue Dx Cellular Analyser Automated Ear Cytology Assessment in Dogs and Cats in Cases of Dermatologist-Diagnosed Otitis Externa

### Methods

Performance of the IDEXX inVue Dx Cellular Analyser compared otitis diagnoses by board-certified dermatologists at a single referral institution. One hundred forty canine and 17 feline ear swab samples were obtained as part of the respective patients' dermatologic examination. Dermatologists diagnosed bacterial, yeast, or inflammatory otitis based on a combination of history, clinical signs, and ear cytology, and they described the results of the ear cytology findings that informed their diagnoses in the patient records made available for the study.

To diminish variability between the sampling site and amount of sample collected, a single ear swab was obtained from the junction of the horizontal and vertical ear canal of each ear. Left and right ears were treated as distinct samples. The swab was first used to make a smear on a glass slide that was air-dried, fixed with methanol, and stained with Romanowsky stains (RAL DIFF-QUIK™). Trained personnel of the dermatology service (either one of two board-certified dermatologists or a trained technician working under the guidance of the dermatologists) performed the subjective assessment of the glass slides. Assessment of yeast, rods, cocci, and WBCs was recorded along with a patient diagnosis. A single operator gathered the same ear sample swab for analysis in the IDEXX inVue Dx analyser, algorithm software version 5.4.5, within 1 hour of collection. Dermatology personnel were blinded to IDEXX inVue Dx analyser results and performed their clinical and cytologic evaluation using a conventional glass-slide method. Clinical information included clinical signs of otitis (e.g., pruritis, discharge, erythema), underlying causes (e.g., aural mass, allergies, autoimmune disease), subjective semiquantitative ear cytology results from glass slide, and clinical interpretation. Of the 157 ear samples, 146 samples were from ears diagnosed with otitis externa, while 11 were noted to be clinically normal.

Ear cytology results were recorded by either a semiquantitative scale (e.g., 0, 1+, 2+) or using terms (e.g., occasional, rare, too numerous to count (TNTC), which were coded into a semiquantitative scale), and they were correlated to semiquantitative analyser results for cocci, rods, and yeast or the presence/absence of WBCs. Kendall's tau-b was used to measure correlation between the two methods as this statistic is robust to nonlinear relationships and can be applied to any mix of ordinal and/or continuous variables. Kendall's tau-b values range between -1 and 1 with 0 representing no tendency to increase or decrease together and 1 representing a perfect positive correlation, i.e., an increase in one variable corresponds to an increase in the other.

### Results and discussion

The IDEXX inVue Dx analyser exhibited a fair positive correlation with dermatologist-diagnosed yeast-, cocci-, and rod-associated otitis, and a moderate positive correlation with the presence of WBCs (table 1).

A limitation of the study is that the dermatologists' diagnoses were based on a single evaluation of a single glass slide, which does not account for the documented variability in glass-slide ear and skin cytologic assessments, even among veterinary dermatology experts as discussed above. This variability likely contributed to discrepancies in diagnostic accuracy and interpretation. Additionally, the use of a single swab to get the same sample onto a glass slide and into the analyser, immediately compromises the comparison because a significant amount of sample is left on the glass slide and not available to the analyser. Still, a fair to moderate positive correlation is comparable to the performance of two readers or the same reader making two interpretations of the same ear or skin slide as noted in the background section of this paper and reflects good performance given the inherent subjectivity and variability of ear cytology.

**Table 1.** Agreement between the IDEXX inVue Dx analyser and dermatologist-diagnosed otitis externa as measured by Kendall's tau-b

Parameter	Kendall's tau-b
Cocci	0.4
Rods	0.4
Yeast	0.4
WBCs	0.5

Conventional ear cytology, characterised by inherent subjectivity and variability, lacks well-defined performance metrics, rendering meaningful comparison to glass-slide methods challenging and prone to error. Thus, the value of an alternative, automated, AI-based analyser lies not in perfectly replicating traditional cytology but in delivering clinically relevant insights.

## Study 2: Performance of the IDEXX inVue Dx Cellular Analyser in Assessment of Ears with Clinical Otitis Externa

### Methods

The correlation of the IDEXX inVue Dx Cellular Analyser output to clinically diagnosed otitis externa was assessed. Dogs presenting to one of six clinics with signs of otitis externa in one or both ears were assessed by the attending veterinarian, and each ear was given an individual clinical score using the Otitis Index Score (OTIS-3) system, which has demonstrated strong inter- and intraobserver reliability in the clinical assessment of dogs with otitis externa.<sup>10</sup> Swabs of the ear canals were then taken and analysed on the IDEXX inVue Dx analyser, algorithm software version 5.4.5. The analyser's ability to detect infection (yeast, rods, or cocci  $\geq 1$ ) was assessed in ears clinically diagnosed with otitis externa using the OTIS-3 system.<sup>10</sup> Inclusion criteria consisted of ears with an OTIS-3 score of 0 and  $\geq 6$  as assessed by the attending veterinarian on the parameters of erythema, exudate, swelling, or ulceration as a surrogate indicator of normal ears and moderate to severely affected ears. Ears with an OTIS-3 score of 1–5 were considered ambiguous for otitis externa and were excluded to account for variability in scoring by different veterinarians and noninfectious causes of abnormalities in canine ears. Each ear was considered separately. Results with error flags

were excluded. In ears with an OTIS-3 score of  $\geq 6$ , findings of “few” were considered significant per current medical recommendations as the ear environment was considered abnormal. In ears with an OTIS-3 score of 0, IDEXX inVue Dx analyser findings of few cocci or few yeast were considered to indicate normal flora because the ears were considered normal.<sup>4</sup>

## Results and discussion

Fifty-seven ear cytology samples from 32 dogs were included in the analysis. Ears with an OTIS-3 score of  $\geq 9$  (up to 12) were considered severely abnormal. Of the 13 severely abnormal ears in the study, the IDEXX inVue Dx analyser reported findings of infection in 12 samples. Ears with an OTIS-3 score of 6–8 were considered moderately abnormal. Of the 38 moderately abnormal ears in the study, the analyser reported findings of infection in 37. Taken together, of the 51 ears scoring moderately to severely clinically abnormal, the IDEXX inVue Dx analyser reported infection in 49, resulting in a sensitivity of 96% (table 2). Of the ears considered clinically normal (OTIS-3 score of 0), 4 out of 6 had no abnormal findings on the analyser. One sample reported as having few cocci and few yeast considered normal flora in healthy ears.<sup>4</sup> One sample reported few cocci and moderate yeast. Therefore, 5 out of 6 clinically normal ears returned no findings of infection from the IDEXX inVue Dx analyser, providing a specificity of 83% (table 2).

**Table 2.** Results of IDEXX inVue Dx analyser output in clinically normal and abnormal ears.

Number of ears (N = 57)	OTIS-3 score	Analyser results	Sensitivity	Specificity
12	9–12	Positive findings	96%	83%
1	9–12	None		
37	6–8	Positive findings		
1	6–8	None		
4	0	None	83%	
1	0	Few cocci, few yeast		
1	0	Few cocci, moderate yeast		

**Note:** Gray shading denotes discordant results for specificity and sensitivity determination.

## References

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These findings demonstrate that cytologic evaluation correlates strongly with clinical severity as determined by the Otitis Index Score (OTIS-3) system. The high sensitivity (96%) of the IDEXX inVue Dx analyser in moderately to severely affected ears supports its reliability as a diagnostic tool for confirming otitis externa and guiding appropriate treatment. In ears with negative clinical scores, the IDEXX inVue Dx analyser demonstrated good specificity (83%), reinforcing its value as a diagnostic test for disease detection and management along with history and clinical signs.

## Conclusion

The IDEXX inVue Dx Cellular Analyser identifies important elements in dog and cat ear samples using its computational power and deep-learning models to produce actionable, automated, algorithm-aided classification and interpretation of ear cytology samples. Additionally, the IDEXX inVue Dx analyser report provides diagnostic considerations on every run to outline the potential clinical significance of its findings and their implications in a patient’s otitis externa, while also providing an objective standard against which to assess a patient’s clinical picture in follow-up visits. The IDEXX inVue Dx analyser automates the process of performing ear cytology, bringing an objective, standardised approach to ear cytology, the primary diagnostic tool in the diagnosis and management of otitis externa in dogs and cats.