Appendix D Table 4. Accuracy of Diagnostic Tests From Studies of Diagnostic Test Accuracy—Clue Cells (KQ 2)

| Author;  Year  Country | Reference Test | N (%) With Confirmed BV on Referent Test | Sensitivity (95% CI) | Specificity (95% CI) | Positive Likelihood Ratio | Negative Likelihood Ratio | Other Comments |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Bradshaw et al100; 2005;  Australia | Gram stain (Nugent score ≥7); participants with intermediate flora were excluded (N=36) | 108 (38) | 0.96 (0.91 to 0.99) | 0.99 (0.96 to 1.00) | 138.67\* | 0.04\* | None |
| Gratacos et al88;†  2005;  Spain | Gram stain (Nugent score ≥7) | 22 (4.5) | 0.59 (NR) | 0.94 (NR) | NR | NR | None |
| Gutman et al109;  2005;  United States | Gram stain (Nugent score ≥7) | 104 (38.7) | 0.74 (0.65 to 0.82) | 0.86 (0.80 to 0.91) | NR | NR | AUC is 0.80. |
| Hay et al91;  1992;  U.K. | Gram stain (Spiegel’s criteria) | 13 (11.4) | 1.00\* (0.77\* to 1.0\*) | 1.00\* (0.96\* to 1.0\*) | Infinite\* | 0.00\* | None |
| Hellberg et al93; 2001; Sweden | Complete Amsel’s clinical criteria | 131 (13.7) | 1.0 (NR) | 0.92 (NR) | NR | NR | None |
| Mastrobattista et al89;‡  2000;  United States | Gram stain (Nugent score ≥7) | 18 (26.9\*) | 0.50 (0.29\* to 0.71\*) | 0.94 (0.84\* to 0.98\*) | 8.17\* | 0.53\* | None |
| Myziuk et al102; 2003;  Canada | Gram stain (Nugent score ≥7) | 12 (21.1\*) | 0.92 (0.65\* to 0.99\*) | 1.00 (0.92\* to 1.0\*) | Infinite\* | 0.08\* | None |
| Platz-Christensen et al92;§  1995;  Sweden | Gram stain (Spiegel’s criteria) | 36 (33.3\*) | 0.92\* (0.78\* to 0.97\*) | 1.00\* (0.95\* to 1.0\*) | Infinite\* | 0.08\* | None |
| Rouse et al136; 2009;  United States | Gram stain (Nugent’s criteria)ǁ | 32 (16.6) | 0.38 (0.22 to 0.56) | 0.91 (0.86 to 0.95) | 4.31\* | 0.68\* | None |
| Schmidt et al94; 1994;  Denmark | Complete Amsel’s clinical criteria | 77 (41.0) of those with discharge complaint; 53 (13.0) of those without discharge complaint | 0.97 (0.91\* to 0.99\*) for those with discharge complaint; 1.00 (0.93\* to 1.0\*) for those without discharge complaint | 0.93 (0.86\* to 0.96\*) for those with discharge complaint; 0.92 (0.89\* to 0.95\*) for those without discharge complaint | 13.51\* for those with discharge complaint; 12.64\* for those without discharge complaint | 0.03\* for those with discharge complaint; 0.00\* for those without discharge complaint | None |
| Schwebke et al108;  1996;  United States | Gram stain (Nugent score ≥7) | 243 (39.4) | 0.60 (0.54 to 0.66) | 0.94 (0.92\* to 0.96\*) | 10.70\* | 0.42\* | Switching from a clue cell threshold of >20% to “any clue cells” results in sensitivity of 0.80 (95% CI, NR) and specificity of 0.79 (95% CI, NR). |
| Schwebke et al99Gaydos et al65;  2018/2017;  United States | Gram stain (Nugent score ≥7); participants with Nugent score 4 to 6 were excluded (N=213) | 783 (50.5\*) | 0.79 (0.76 to 0.81) | 0.86 (0.83 to 0.89) | 5.78\* | 0.25\* | None |

\* Indicates values that we calculated based on data provided in the study.

† Study used any clue cells for positive diagnosis.

‡ Study used any clue cells for positive diagnosis.

§ Study authors report sensitivity and specificity for clue cells as the referent test and Gram Stain as the index test.

ǁ Scoring system is not explicitly stated but assumed to be Nugent.

**Abbreviations:** AUC=area under the curve; BV=bacterial vaginosis; CI=confidence interval; KQ=key question; N=number of participants; NR=not reported; U.K.=United Kingdom.