Correlation Data From Salivary Multi Test Using SillHa Oral Wellness System

Seven analytes were chosen as markers for the following conditions: [Dental Caries] cariogenic bacteria, acidity and buffer capacity; [Periodontal disease] protein, blood, leukocyte; [Oral cleanliness] ammonia. The seven (7) analytes on SillHa paper (test strip) were measured against standard control methods as follows: resazurin reduction method for cariogenic bacteria (RD test), pH meter was used as the control method for pH and buffer capacity, latex immune agglutination turbidometry method for blood and leukocyte, dye-binding method for protein, and an enzyme method using glutamate dehydrogenase for ammonia.

Correlations between these standard methods and clinical test results of dental caries, periodontal disease and oral cleanliness have been indicated in many studies. [i] [ii] [iii]

In a 2012 study conducted by LION corporation and ARKRAY,[iv] 231 volunteers (Male: 93, Female:138; Age: 40.3 ± 12.8) were tested with the newly developed Salivary Multi- test system (AL-55) and compared with standard methods. The measured values were divided into 3 groups (Low, Average, High) which provided easy-to-understand test results for patients. The concordance (agreement) rates between the values measured by standard method and reflectance measured by AL-55 for all seven analytes were from 70 – 90% indicating high validity and reliability. They were 70% (cariogenic bacteria), 82% (pH), 73% (Buffer capacity), 71% (blood), 72% (leukocyte), 84% (protein), and 90% (ammonia).

To further confirm the accuracy of the SillHa system, an additional correlation test was performed with oral rinse samples from 105 volunteers (Male:68, Female:37) in September 2015 to confirm correlation to control methods. Three lots of strips were tested. Using the same

3-group stratification (Low, Average, High) the concordance (agreement) rates were calculated. The concordance rate for cariogenic bacteria was 75% exact match and 99% overall match within one rank against the control method, and the remaining analytes were ≥ 98% match within one rank of the standard method.

Correlation between the test method (SillHa paper) and reference (standard) method was also calculated using Pearson correlation coefficient (r) (which is a measure of the linear correlation between the two variables X and Y). The closer the (r) value is to 1.0 the higher the correlation between the two methodologies. Table 1 shows the average correlation coefficient calculated for seven analytes from the two studies referenced above.

Table 1: Correlation coefficients measured from two studies

Measured analyte	Correlation coeff (r) [2012]	Correlation coeff (r) [2015]
Cariogenic bacteria	0.59	0.44
pH	0.74	0.72
Buffer capacity	0.86	0.88
Blood	0.74	0.65
Leukocyte	0.67	0.71
Protein	0.75	0.79
Ammonia	0.89	0.97

The two studies had comparable correlation coefficients for the seven analytes measured as described.

Mid to high level correlation was confirmed between SillHa and standard methods by the above two studies ($p < 0.01$ for all seven analytes). Salivary multi-test using SillHa Oral Wellness System may be useful as an education tool for motivating patients in dental clinics about treatment

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and self-care, as well as a screening tool in dental health examination at schools and clinics by taking advantage of its ability to obtain multiple results in the short time of 5 minutes.

References

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