

Quantitative collection/purification and analysis of saliva analytes in a POC setting.

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Oasis Diagnostics has developed two products to address the need for providing a saliva sample for use in final quantitative analysis of relevant biological analytes in a Point-of-Care (POC) or Point-of-Use (POU) environment.

The first product is a real-time quantitative POC/POU Salivary Cortisol test (VerOFy®) that utilizes a fluorescent Lateral Flow Test (LFT) cassette in combination with a Saliva Collection/Purification device. The LFT cassette is then quantitated with a Litebox Image Analysis System (LIAM) which detects the fluorescent bands on the LFT strip. Image Analysis and data transfer is accomplished with an onboard processor, and bluetooth internet data transfer. Each cassette is recognized for test analyte, and lot specific information via QR codes and transferred to the processor on the LIAM. LIAM instrument controls are simple, easy to use, and results are visualized on the onboard screen. The cortisol assay can detect cortisol values in saliva within a standard range of 0.5-15 ng/ml. Total collection and analysis time is approximately 20 minutes. Adequate sample is collected to have remnant sufficient for retain or confirmation.

The second product is the Oasis Accu•SAL™ Saliva Collection/Transport device (AS). The AS device was developed to provide an easy to use saliva collection device, which can be placed into a buffer tube, and transported to a lab for analysis of various analytes, including Drugs of Abuse. For transport use, the tube is inverted 4-5 times before shipment. However, the AS can also be used in a POC/POU setting by increasing the number of inversions to insure complete and reproducible extraction and mixing of the saliva sample from the collection pad. The AS has an onboard Sample Volume Adequacy Indicator (SVAI) to signal when collection is complete. Average collection values range from 0.65-1.1 ml, with the overwhelming majority falling between 0.75-0.90 ml. The tube has a volume scale printed on the tube, that can discriminate the volume (+/- 20-40ul) remaining in the tube after removal of the collection strip. From that information an accurate volume of saliva collected and the dilution factor can be calculated. The dilution determination is essential in providing accurate values for downstream testing, since the collection volume in this and other saliva collection devices can display wide ranges in recovery depending upon saliva viscosity and other factors.