Semi-quantitative Readout in a Paper-based Test for the Home Monitoring of Phenylalanine Levels in Phenylketonuria Patients

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Phenylketonuria (PKU) is an inherited genetic disorder that results in increased levels of an amino acid called phenylalanine (Phe) in the blood. If PKU is not diagnosed and treated, the Phe build up can lead to mental disabilities and other serious health problems. The most common therapy for individuals with PKU is a strict diet to achieve target Phe levels in the blood. Thus, monitoring Phe levels in the blood of these individuals is a critical component of therapy. Existing tests for PKU require high-resource laboratories, which are not available to many populations and cannot provide the real-time feedback required for effective therapy monitoring. In many regions of the world, the level of resources is too low to support testing that requires any instrumentation. It would be ideal to develop an instrument-free, rapid and simple test for PKU patients to monitor their Phe levels. We are developing a paper-based test that provides a semi-quantitative output of the concentration of Phe from a sample of blood. Users will be able to measure the concentration of Phe in a blood sample by looking at the simple pattern or intensity of color produced and matching it to the expected result for “low”, “medium”, or “high” levels of Phe. The focus of this presentation is on the demonstration of the use of colorimetric indicators to achieve distinct visible output for clinically relevant concentration ranges of Phe in a sample. Specifically we are optimizing reagent concentrations to produce the most robust signal and evaluating different colorimetric indicators to determine which indicators produce the ideal response curves (signal vs. Phe concentration) for quantitative readout. The ideal intensity-based response curve should have a steep slope to produce the greatest difference for a specific difference in Phe levels. In addition to the presentation of this data, future plans for the incorporation of the readout developed into a simple disposable test will be described.