# Retinol Binding Protein Enzyme Immunoassay (RBP-EIA)

## Health need

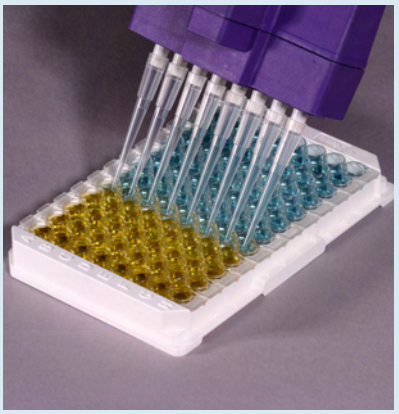
For almost 50 years, researchers have known that administering oral doses of vitamin A could prevent the consequences of severe vitamin A deficiency (VAD)—including blindness and death. Analysis of over 150,000 children between the ages of six months and five years from several countries in which VAD is a concern indicate that almost one-quarter of early childhood deaths, especially related to diarrhea and measles, could be prevented by vitamin A (retinol) supplementation. Public health planners and researchers need easier, less expensive ways to assess the extent of VAD among populations to inform public policies and promote well-targeted supplementation programs. Strategies for controlling VAD aim to provide adequate intake through dietary improvement, fortification, and supplementation. To identify the optimal mix of strategies and to monitor progress, reliable information on the magnitude and distribution of VAD in populations is needed. The current tools to do so are expensive and require external assistance; simpler, less-expensive, field-appropriate tools are needed.

## Technology solution

RBP has been shown to be a surrogate indicator for retinol, an accepted indicator of vitamin A status. The RBP-EIA was developed by PATH as an easy way to detect and quantify RBP using human plasma or serum. The test is rapid; results are available within 40 minutes. It can be read on a standard or portable EIA reader, and the results are calculated based on values from calibrator control sera provided with the kit. The RBP-EIA has been designed to produce data rapidly; to reduce reliance on costly, centralized laboratory facilities; and to provide an effective tool for field monitoring of VAD in at-risk populations. Laboratory validation has shown a strong correlation between the results obtained by the RBP-EIA and retinol, as determined by high-performance liquid chromatography (HPLC), when serum is used. The RBP-EIA has also demonstrated a strong correlation to HPLC using samples collected from a population of children at risk of VAD. The RBP-EIA predicted a VAD prevalence of 20.2 percent, while the use of HPLC determined the prevalence to be 20.4 percent. A 2004 field evaluation conducted in Thailand demonstrated that RBP is a good surrogate of retinol in both venous and capillary blood samples to estimate VAD in preschool children. Results from experiments using dried blood spots as a sample for the RBP-EIA demonstrated a positive correlation.

## Current status and results

PATH successfully licensed its RBP-EIA technology to Scimedx, a US diagnostic device manufacturer, for introduction to commercial markets. As of 2011, over 700 test kits had been distributed to support the assessment of nearly 30,000 samples through the Demographic Health Surveys in Uganda, Tanzania, and other academic research institutions. Scimedx continues to support RBP-EIA availability as part of their commercial strategy to stock and supply test kits for orders requiring relatively small quantities for specialized use in diagnostic or surveillance activities.



**Simple, less-expensive test for vitamin A deficiency.**

**"The potential for local assessment of vitamin A serum concentrations through RBP determination is promising. This would bring an accurate and simple vitamin A assessment methodology into the 'toolbox' of local public health workers."**

Tanumihardjo SA, Blaner WS, Jiang T. Dried blood spot retinol and retinol-binding protein concentrations using enzyme immunoassay as surrogates of serum retinol concentrations. *MOST Technical Report,* June 2002.

## Availability

Tests can be ordered from Caryn Shapiro, Scimedx, New Jersey, cshapiro@scimedix.com. For more information regarding this project, contact Ralph Schneideman at rschneideman@path.org.

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