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(12) **United States Patent**
Buchanan

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(54) **METHODS AND DEVICES TO ENHANCE SENSITIVITY AND EVALUATE SAMPLE ADEQUACY AND REAGENT REACTIVITY IN RAPID LATERAL FLOW IMMUNOASSAYS**

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(65) **Prior Publication Data**

US 2011/0143365 A1 Jun. 16, 2011

Hodinka, R., et al., "Detection of Human Immunodeficiency Virus Antibodies in Oral Fluids," Clinical and Diagnostic Laboratory Immunology 5(4):419-426, Jul. 1998.

Related U.S. Application Data

(Continued)

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(51) **Int. Cl.**

G01N 33/558 (2006.01)

(57) **ABSTRACT**

(52) **U.S. Cl.** **436/514**; 422/401; 422/420; 422/425; 422/430; 435/5; 435/287.2; 435/287.7; 435/287.9; 435/288.2; 435/810; 435/970; 436/525; 436/526; 436/530; 436/531; 436/805; 436/807; 436/810

Methods and devices for rapid lateral flow immunoassays to detect specific antibodies within a liquid sample while also validating the adequacy of the liquid sample for the presence of immunoglobulin and the integrity and immunoreactivity of the test reagents that detect the antibodies of interest, without requiring instrumentation. The methods and devices provide for delivery of a diluted liquid sample to a single location that simultaneously directs the liquid flow along two or more separate flow paths, one that serves as a positive control to confirm that all critical reagents of the test are immunoreactive, and that the sample being tested is adequate, and the other to detect specific antibodies if present.

(58) **Field of Classification Search** None
See application file for complete search history.

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30 Claims, 22 Drawing Sheets

