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(54) **SANITARY SWAB COLLECTION SYSTEM,
MICROFLUIDIC ASSAY DEVICE, AND
METHODS FOR DIAGNOSTIC ASSAYS**

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(58) **Field of Classification Search** 435/308.1,
435/309.1, 309.2

See application file for complete search history.

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(57) **ABSTRACT**

Biohazard specimen collection containers are provided with
an external disposable skin, that is stripped away and dis-
carded after the biohazardous specimen is collected, thus
reducing or eliminating objectionable or dangerous residues
on the outside surfaces of the container. Further, we teach that
the sample collection container with external disposable skin
may also serve as an integrated microfluidic biosample pro-
cessing and analytical device, thereby providing a single
entry, disposable assay unit, kit and system for "world-to-
result" clinical diagnostic testing. These integrated assay
devices are provided with synergic, multiple safe-handling
features for protecting healthcare workers who handle them.
The modified collection containers and analytical devices
find application, for example, in PCR detection of infectious
organisms or pathogenic markers collected on a swab.

6 Claims, 14 Drawing Sheets

COLLECT A SPECIMEN ON A SWAB;

**INSERT THE SWAB TIP INTO COLLECTION DEVICE,
THE COLLECTION DEVICE HAVING BEEN PROVIDED
WITH DISPOSABLE EXTERNAL SKIN OR SKINS;**

**BREAK OFF THE SWAB HANDLE, AND SEAL THE SWAB
INSIDE THE COLLECTION DEVICE USING A LOCKING,
SEALABLE CLOSURE;**

**REMOVE THE DISPOSABLE SKIN OR SKINS FROM THE
EXTERNAL SURFACES OF THE DEVICE, AND DISCARD;**

**THEN [OPTIONALLY], PERFORM A DIAGNOSTIC ASSAY
ON THE CAPTIVE SPECIMEN.**