Identify organism for testing

Determine requirements for assay (number of samples to be screened, sensitivity, specificity etc.)

Literature and internet searches (see Table x)

Evaluate resources available or can be made available for testing

Consider in house research and development for new test

No

Identify preferred diagnostic methodology (e.g. ELISA, PCR, Bioassay)

Does a suitable previously published assay exist?

Yes

Identification of most appropriate assay

Pilot scale test of assay

Assay satisfies initial requirements?

No

Improvement by minor adjustment?

Yes

Full validation

Method satisfies initial requirements?

No

Improvement by minor adjustment?

Yes

Develop standard operating procedure(s) for assay

Continued monitoring of assay performance (blind testing, proficiency testing, ring testing).

Figure 1. Flowchart for identifying and implementing a new diagnostic assay