Potential Parvovirus Antibody Assay Device Reclassification

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Potential reclassification of qualitative serology-based Parvovirus B19 antibody in vitro diagnostic devices indicated for use to aid in the diagnosis of past or current infection with human parvovirus B19 from Class III to Class II with special controls

Purpose of This Panel Session

- The purpose of this meeting is to discuss the potential future reclassification of Parvovirus antibody assays. FDA is seeking recommendations from the Panel members and the public on whether sufficient information exists such that the development of special controls (which along with general controls) could mitigate the risks from these devices such that the devices would provide a reasonable assurance of safety and effectiveness and therefore, can be eligible for a Class II designation.

Parvovirus B19 Assays: Intended Use

- Parvovirus B19 Antibody Assays:
  - Intended for the detection of IgM antibodies and IgG antibodies evidence of Parvovirus B19 virus infection and may be used to aid in the diagnosis of past or current infection with Parvovirus B19.
  - The clinician should consider the results of these assays as presumptive for risk of fetal infection with Parvovoris B19. The test may be used for all patients as an aid in the diagnosis of fifth disease (erythema infectiosum).

Clinical Aspects: Public Health Burden

- Parvovirus infection occurs worldwide and peaks in late winter/early summer in the United States. Most individuals are infected during school years, with 50 to 80% IgG seroprevalence reported in serosurveys.
- The virus bears a direct cytotoxic effect on erythroid cells and can lead to anemia/a decrease in hemoglobin during infection.

Clinical Aspects: Risks to Health

- False non-reactive result, incorrectly operating device causing false non-reactive result, and incorrectly interpreting result as non-reactive results
  - Spreading of virus to others
  - Improper patient management
  - Concerning in immunocompromised and pregnant women passing virus to fetus
- False reactive result, incorrectly operating device causing false reactive results, and incorrectly interpreting result as reactive result
  - Unnecessary isolation of individuals
  - Unnecessary psychological stress

Risks to Health

- Special Controls to mitigate the risks to health discussed on the previous slide
- Goal: Maintain consistent high performance:
  - (1) Across devices with similar Intended Uses
  - (2) For individual devices over the Total Product Life Cycle (TPLC)

Specific Considerations for Parvovirus Antibody Devices

- Few Parvovirus serology tests on the market may lead to difficulty formulating a composite comparator
- Low prevalence of Parvovirus IgM presence leads to difficulty in enrollment of clinical and analytical studies
- Cross-reactivity and interfering substances

Additional Considerations

- Manufacturers would no longer be regulated under the Class III paradigm but instead under the Class II paradigm, which has fewer regulatory requirements.
- FDA, on its own initiative, is contemplating reclassifying these postamendments Class III devices into Class II. FDA believes that, when used as indicated, Parvovirus antibody tests can provide significant benefits to clinicians and patients, including making a serological determination of past, recent, or current infection with Parvovirus B19, as an aid in the diagnosis of fifth disease (erythema infectiosum), and presumptive for risk of fetal infection with Parvovirus B19

Questions for the Panel

1. Please comment on whether you believe FDA has identified a complete and accurate list of the risks to health presented by Parvovirus antibody assays.

   Please comment on whether you disagree with any of these identified risks or whether you believe any other risk should be included in the overall risk assessment of Parvovirus antibody assays.

2. Please discuss potential mitigation measure(s)/control(s) that FDA should consider that could mitigate each of the identified risks.

3. Based upon the information presented and future discussion at this panel meeting, please discuss whether, based on the available information, the Panel believes FDA should initiate the reclassification process for these devices from Class III to Class II, subject to special controls.


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