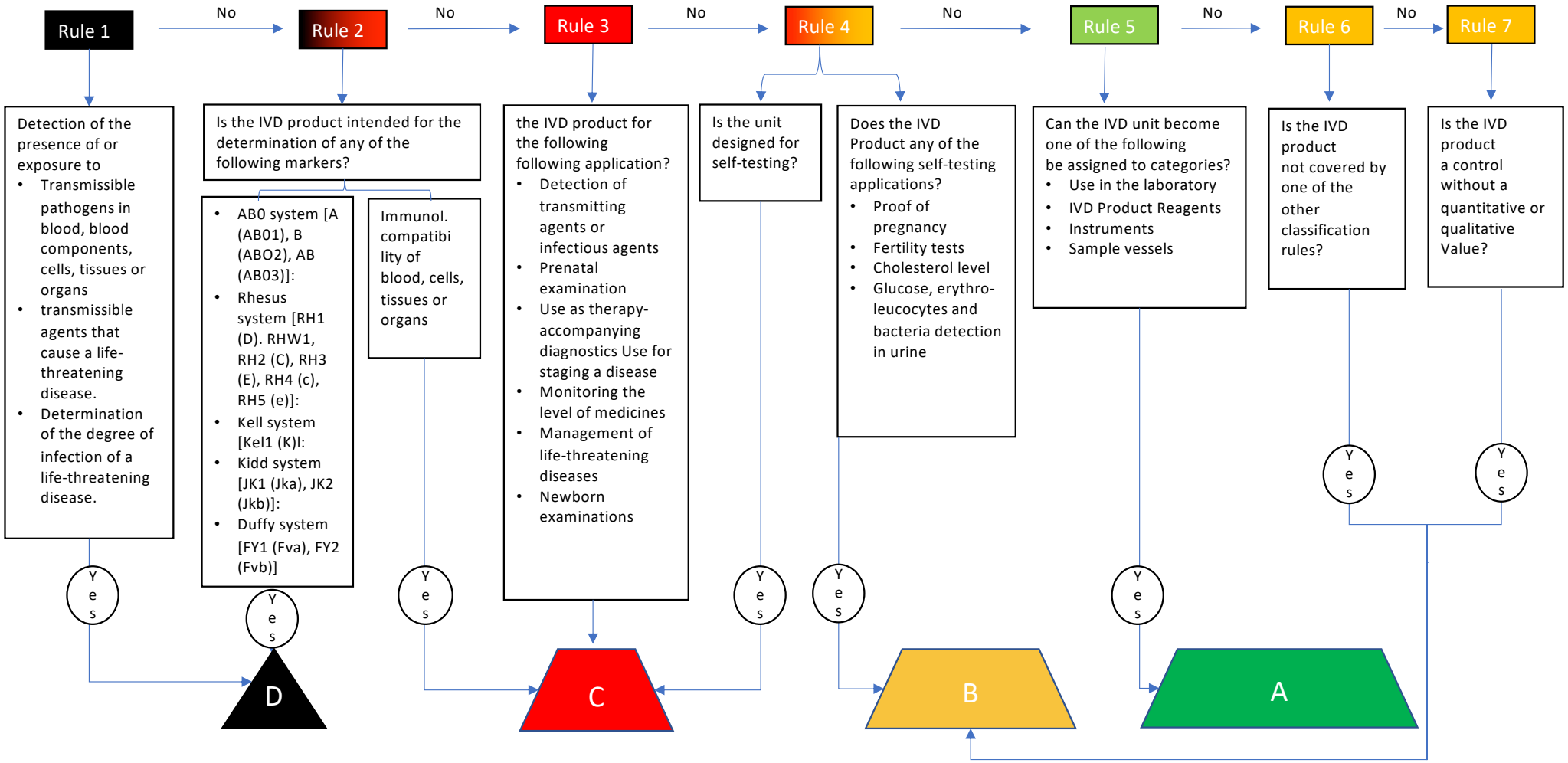
Rule 1
No
Rule 2
No
Rule 3
No
Rule 4
No
Rule 5
No
Rule 6
No
Rule 7
Detection of the presence of or exposure to
• Transmissible pathogens in blood, blood components, cells, tissues or organs
• transmissible agents that cause a life-threatening disease.
• Determination of the degree of infection of a life-threatening disease.
Is the IVD product intended for the determination of any of the following markers?
• AB0 system [A (AB01), B (ABO2), AB (AB03)]:
• Rhesus system [RH1 (D). RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]:
• Kell system [Kel1 (K)l:
• Kidd system [JK1 (Jka), JK2 (Jkb)]:
• Duffy system [FY1 (Fva), FY2 (Fvb)]
Immunol. compatibi lity of blood, cells, tissues or organs
the IVD product for the following following application?
• Detection of transmitting agents or infectious agents
• Prenatal examination
• Use as therapy-accompanying diagnostics Use for staging a disease
• Monitoring the level of medicines
• Management of life-threatening diseases
• Newborn examinations
Is the unit designed for self-testing?
Does the IVD Product any of the following self-testing applications?
• Proof of pregnancy
• Fertility tests
• Cholesterol level
• Glucose, erythro-leucocytes and bacteria detection in urine
Can the IVD unit become one of the following be assigned to categories?
• Use in the laboratory
• IVD Product Reagents
• Instruments
• Sample vessels
Is the IVD product not covered by one of the other classification rules?
Is the IVD product a control without a quantitative or qualitative Value?
Yes
Yes
Yes
Yes
Yes
Yes
Yes
D
C
B
A