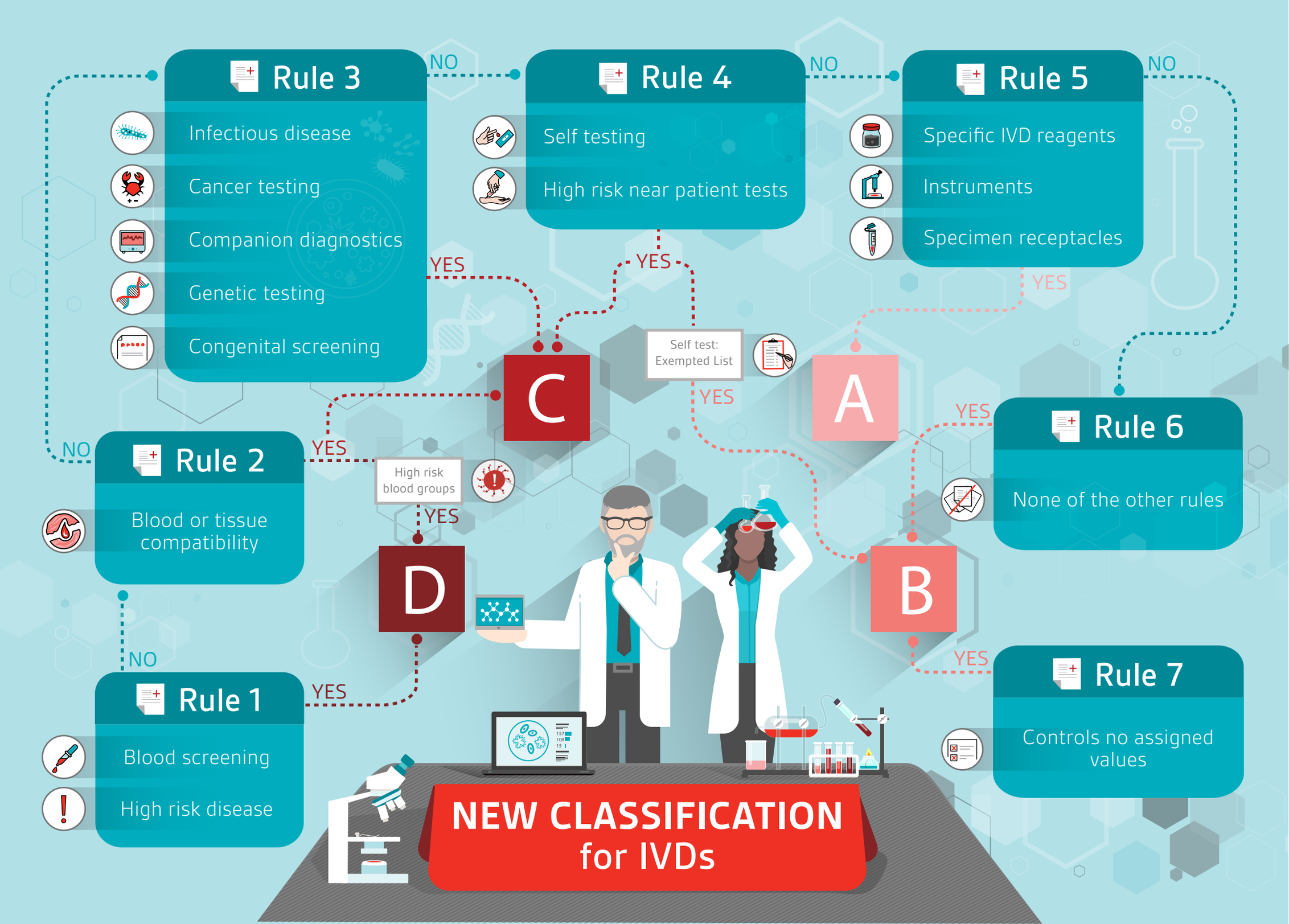
Rule 3
Infectious disease
Cancer testing
Companion diagnostics
Genetic testing
Congenital screening
NO
Rule 4
Self testing
High risk near patient tests
NO
Rule 5
Specific IVD reagents
Instruments
Specimen receptacles
NO
YES
YES
YES
Self test: Exempted List
YES
C
A
YES
Rule 6
None of the other rules
NO
Rule 2
Blood or tissue compatibility
YES
High risk blood groups
YES
D
B
NO
Rule 1
Blood screening
High risk disease
YES
YES
Rule 7
Controls no assigned values
NEW CLASSIFICATION
for IVDs