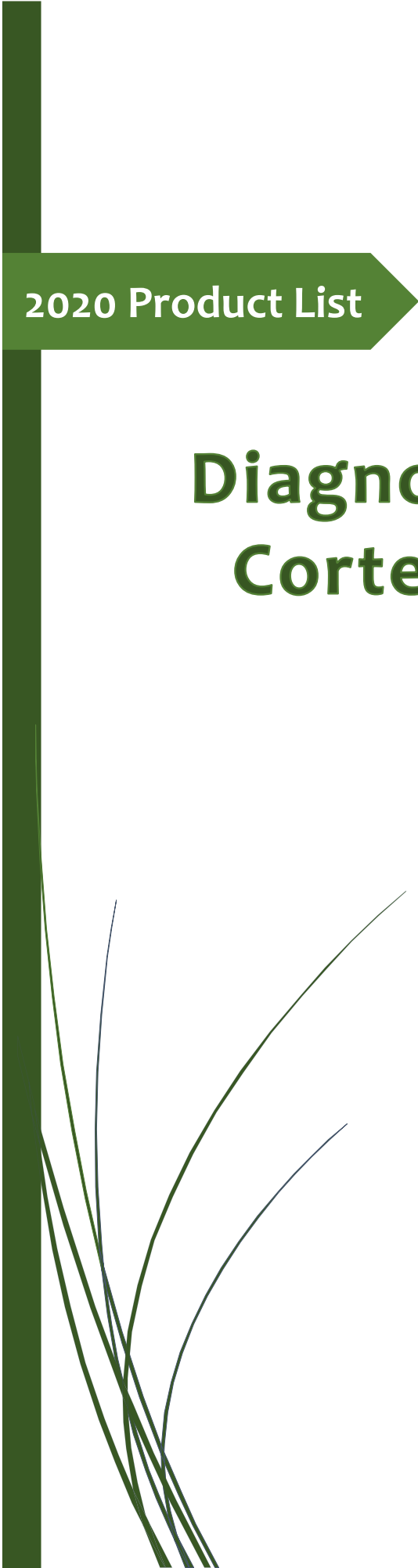


A thick dark green vertical bar runs down the left side of the page. A dark green arrow points to the right from this bar, containing the text '2020 Product List'. At the bottom left, there is a stylized plant graphic with several thin, curved lines in dark green and blue.

**2020 Product List**

# **Diagnostic Automation / Cortez Diagnostic Inc.**

## **IFA**

DA/CD

## IFA

| Product Name                                                                       | Catalog # | # of Tests | CE | FDA | Qualitative / Quantitative | Assay Time | Sensitivity |
|------------------------------------------------------------------------------------|-----------|------------|----|-----|----------------------------|------------|-------------|
|  |           |            |    |     |                            |            |             |

## Autoimmune Diseases and Others

|                                                                     |          |               |   |         |                                   |         |      |
|---------------------------------------------------------------------|----------|---------------|---|---------|-----------------------------------|---------|------|
| AccuDiag™ ANA Rat Liver IFA Kit                                     | 210708D  | 10 x 6 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ ANA Mouse Kidney IFA Kit                                  | 220708D  | 10 x 8 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ ANA HEP-2 IFA Kit                                         | 231005D  | 10 x 12 wells | ✓ | Cleared | Semi-Quantitative/<br>Qualitative | ~80 min | 100% |
| AccuDiag™ ANA HEP-2 IFA Kit                                         | 230512D  | 25 x 12 wells | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ ANA HEP-2 IFA Kit with Evans Blue                         | 231005DE | 10 x 12 wells | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ ANA HEP-2 IFA Kit with Evans Blue                         | 230512DE | 25 x 12 wells | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ AMA (Anti-mitochondrial Antibody) IFA Kit                 | 240806D  | 10 x 6 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ AAS Rat Kidney/Stomach Tissue Test System IFA Kit         | 250608D  | 10 x 8 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ AAS Rat Kidney/Stomach/Liver Tissue Test System IFA Kit   | 250609D  | 10 x 8 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ AAS Mouse Kidney/Stomach/Liver Tissue Test System IFA Kit | 250610D  | 10 x 8 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ ASMA (Anti-smooth muscle Antibody) IFA Kit                | 260806D  | 10 x 6 wells  | ✓ | Cleared | Semi-Quantitative                 | ~80 min | 100% |
| AccuDiag™ ATA (Anti-thyroid Antibody) IFA Kit                       | 270806D  | 10 x 6 wells  | ✓ | Cleared | Semi-Quantitative                 | ~85 min | 100% |
| AccuDiag™ ASA (Anti-skin Antibody) IFA Kit                          | 280806D  | 10 x 6 wells  | ✓ | Cleared | Semi-Quantitative                 | ~85 min | 100% |

## IFA

| Product Name           | Catalog # | # of Tests   | CE | FDA     | Qualitative / Quantitative     | Assay Time | Sensitivity |
|------------------------|-----------|--------------|----|---------|--------------------------------|------------|-------------|
| AccuDiag™ nDNA IFA Kit | 320608D   | 10 x 8 wells | ✓  | Cleared | Qualitative/ Semi-Quantitative | ~80 min    | N/A         |

### Bacterial Diseases

|                                                         |             |               |   |         |                   |          |      |
|---------------------------------------------------------|-------------|---------------|---|---------|-------------------|----------|------|
| AccuDiag™ Legionella Antibody IFA Kit (Group 1-6)       | 331008-6D   | 10 x 8 wells  | ✓ | Cleared | Semi-Quantitative | ~80 min  | 100% |
| AccuDiag™ FTA-ABS Double Stain (Syphilis) IFA Kit       | 351010-DS   | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~115 min | 100% |
| AccuDiag™ FTA-ABS (Syphilis) Titratable IFA Kit         | 351010-T    | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~130 min | 100% |
| AccuDiag™ FTA-ABS (Syphilis) IFA Kit                    | 351010      | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~130 min | 100% |
| AccuDiag™ B. burgdorferi (Lyme Disease) IgG/IgM IFA Kit | 361010-G/MD | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~80 min  | 100% |



### Viral Disease

|                               |           |               |   |         |                   |         |      |
|-------------------------------|-----------|---------------|---|---------|-------------------|---------|------|
| AccuDiag™ CMV IgG IFA Kit     | 371010-G  | 10 x 10 wells |   | Cleared | Semi-Quantitative | ~80 min | 100% |
| AccuDiag™ CMV IgM IFA Kit     | 371010-M  | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~80 min | 100% |
| AccuDiag™ HSV-1 IgG IFA Kit   | 381010-G  | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~80 min | 100% |
| AccuDiag™ HSV-2 IgG IFA Kit   | 391010-G  | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~80 min | 100% |
| AccuDiag™ EBV-VCA IgG IFA Kit | 401010-G  | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~80 min | 100% |
| AccuDiag™ EBV-VCA IgM IFA Kit | 401005-MD | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~90 min | 100% |
| AccuDiag™ EBV-EA IFA Kit      | 401010-EA | 10 x 10 wells | ✓ | Cleared | Semi-Quantitative | ~80 min | 100% |

| <b>IFA</b>                                   |                  |                   |           |            |                                   |                   |                    |
|----------------------------------------------|------------------|-------------------|-----------|------------|-----------------------------------|-------------------|--------------------|
| <b>Product Name</b>                          | <b>Catalog #</b> | <b># of Tests</b> | <b>CE</b> | <b>FDA</b> | <b>Qualitative / Quantitative</b> | <b>Assay Time</b> | <b>Sensitivity</b> |
| AccuDiag™ EBV-NA IgG IFA Kit                 | 401010-NA        | 10 x 10 wells     | ✓         | Cleared    | Semi-Quantitative                 | ~80 min           | 100%               |
| AccuDiag™ Measles IgG IFA Kit                | 250611D          | 10 x 10 wells     | ✓         | Cleared    | Qualitative/ Quantitative         | ~80 min           | 100%               |
| AccuDiag™ Varicella-Zoster Virus IgG IFA Kit | 421010-G         | 10 x 10 wells     | ✓         | Cleared    | Semi-Quantitative                 | ~80 min           | 100%               |
| <b>Parasitic Disease</b>                     |                  |                   |           |            |                                   |                   |                    |
| AccuDiag™ Toxoplasma IgG (T. Gondii) IFA Kit | 431508-GD        | 10 x 8 wells      | ✓         | Cleared    | Qualitative/ Semi-Quantitative    | ~80 min           | 100%               |
| AccuDiag™ Toxoplasma IgM (T. Gondii) IFA Kit | 431508-MD        | 10 x 8 wells      | ✓         | Cleared    | Qualitative/ Semi-Quantitative    | ~110 min          | 100%               |
| <b>Ancillary Products</b>                    |                  |                   |           |            |                                   |                   |                    |
| Green Diluent for IFA                        | GDILUENT         | 2 x 25 mL         |           | N/A        | N/A                               | N/A               | N/A                |