



Biocare Medical LLC

EC Declaration of Conformity

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| Date of Issue: | 21 April 2022 |
| Certificate Reference: | All Biocare IVD products are self-declared for compliance to Annex III of the IVDD. None contain any analytes listed in Annex II List A or B |
| Directive: | 98/79/EC IVD Directive of 27 October 1998 |
| Conforming Product: | See attached Product List |
| Manufacturer: | Biocare Medical LLC 60 Berry Drive, Pacheco, CA 94553, U.S.A |
| Authorized Representative: | Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands +31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com |
| Other standards applied: | 1. EN ISO 13485:2016 Medical Devices – QMS- Requirements for Regulatory Purposes 2. ISO 14971 Medical Devices - Application of Risk Management to Medical Devices |

Biocare Medical declares that the above-mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

Signed: *Veronica Runyan*

Veronica Runyan, Director Regulatory Affairs
Biocare Medical LLC



Biocare Medical LLC

| Collective Term | Part Number (s) | Description |
|-----------------|-----------------------|--|
| CT946 | TWN20 | 20% Tween 20 |
| CT907 | GM601 | 4plus Biotinylated Goat Anti-Mouse IgG |
| CT907 | GR602 | 4plus Biotinylated Goat Anti-Rabbit IgG |
| CT907 | GR608 | 4plus Biotinylated Goat Anti-Rabbit IgG (Mouse and rat adsorbed) |
| CT907 | GU600 | 4plus Biotinylated Universal Goat Link |
| CT907 | HP504UM | 4plus HRP Universal Detection |
| CT907 | HP504US | 4plus HRP Universal Detection |
| CT907 | AP605 | 4plus Streptavidin AP Label |
| CT907 | HP604 | 4plus Streptavidin HRP Label |
| CT907 | AP506US | 4plus Universal AP Detection |
| CT1056 | ACI/API3138 | Adipophilin |
| CT1056 | ACI/API3041 | ALK [5A4] |
| CT1056 | CP/PP028 | Alpha-1-Fetoprotein (AFP) |
| CT1056 | CM/PM125 | Amyloid A |
| CT1056 | PP132 | Amyloid P |
| CT1056 | ACI/API109 | Androgen Receptor |
| CT943 | CB910 | Antigen Decloaker, 10X |
| CT907 | OPRI6006 | Antigen Retrieval 1 (AR1) |
| CT907 | ORI6006 | Antigen Retrieval 1 (AR1), high pH |
| CT907 | ORI6005 | Antigen Retrieval 2 (AR2), low pH |
| CT946 | ADP1002 | Aqua DePar, 10X |
| CT1056 | ACI/API/ OAI /AVI3058 | Arginase-1 |
| CT946 | TWA20 | Automation Tween 20, 20X |
| CT946 | AB972 | Avidin-Biotin Kit |
| CT907 | BE965 | Background Eraser |
| CT907 | BP974 | Background Punisher |
| CT907 | BS966 | Background Sniper |
| CT907 | BT967 | Background Terminator |
| CT215 | BJP811 | Bajoran Purple Chromogen Kit |
| CT1056 | ACI/API/ALI3247 | BAP1 |
| CT1056 | ACI/API/3241 | BCA-225 [Cu-18] |
| CT1056 | AVI/OPAI003 | Bcl-2 |
| CT1056 | CM/PM/IP/OAI003 | Bcl-2 |
| CT1056 | AVI410 | Bcl-6 [LN22] |
| CT1056 | CM/PM/OAI410 | Bcl-6 [LN22] |
| CT1056 | OPAI410 | Bcl-6 [LN22] |
| CT1056 | AVI/ALI107 | Ber-EP4 |
| CT1056 | PM/OAI107 | Ber-EP4 |

| Collective Term | Part Number (s) | Description |
|-----------------|--------------------|---|
| CT946 | DS900 | Betazoid DAB Buffer |
| CT215 | BDB2004 | Betazoid DAB Chromogen Kit |
| CT1056 | CM/PM418 | BOB-1 |
| CT943 | BD1000 | Borg Decloaker, RTU |
| CT1056 | AVI3248 G | BRAF V600E [VE1] |
| CT1056 | CM345 | BRCA-1 |
| CT1056 | AVI3203DSK | Breast Cocktail (CK HMW/p63 + CK7/8/18) |
| CT1056 | CM/PM101 | CA 125 |
| CT1056 | AVI123 | CA 19-9 |
| CT1056 | CM/PM123 | CA 19-9 |
| CT1056 | CP/PP072 | Calcitonin |
| CT1056 | CM/PM172 | Calponin |
| CT1056 | OPAI092 | Calretinin |
| CT1056 | CP/PP/IP/OAI092 | Calretinin |
| CT1056 | CM/PM058 | Carcinoembryonic Antigen (CEA {M}) |
| CT1056 | CP/PP/IP009 | Carcinoembryonic Antigen (CEA {P}) |
| CT215 | DBC859 | Cardassian DAB Chromogen Kit |
| CT907 | TRP955 | Carezyme I: Trypsin Kit |
| CT907 | PEP956 | Carezyme II: Pepsin |
| CT907 | PRT957 | Carezyme III: Pronase Kit |
| CT907 | CP/PP229 | Caspase-3 (Cleaved) |
| CT215 | CATHE | CAT Hematoxylin |
| CT1056 | OPAI/ALI/AVI129 | CD10 |
| CT1056 | CM/PM/IP/OAI129 | CD10 |
| CT1056 | API3212 | CD10 [UMAB236] |
| CT1056 | ACI/API3117 | CD103 (RM) |
| CT1056 | CME/PME/IP/ OAI296 | CD117/c-kit |
| CT1056 | ALI/OPAI296 | CD117/c-kit |
| CT1056 | ACI/API3122 | CD11c (Leu-M5) |
| CT1056 | ACI/API3201 | CD137 |
| CT1056 | ACI/API3264 | CD137 [BLR051F] |
| CT1056 | CM/PM/IP167 | CD138 |
| CT1056 | API3193DS | CD138 + Cyclin D1 |
| CT1056 | API3169DS | CD138 + Ki-67 |
| CT1056 | CM/PM029 | CD15 [MMA] |
| CT1056 | CM/PM/IP/OAI073 | CD15 Cocktail |
| CT1056 | CM/PM/OAI353 | CD163 |
| CT1056 | CM/PM310 | CD19 |
| CT1056 | ACI/API3158 | CD1a [O10] |
| CT1056 | ALI/OPAI004 | CD20 [L26] |

| Collective Term | Part Number (s) | Description |
|-----------------|----------------------|----------------------------|
| CT1056 | CM/PM/IP/OAI004 | CD20 [L26] |
| CT1056 | CT1056CM/PM/OAI142 | CD21 |
| CT1056 | CM/PM CT1056169 | CD22 |
| CT1056 | ACI/API3229 | CD22 |
| CT1056 | CM/PM/OAI100 | CD23 |
| CT1056 | ACI/API3268 | CD247 [BL-336-1B2] |
| CT1056 | CME/PME324 | CD3 |
| CT1056 | OPAI324 | CD3 |
| CT1056 | ACI/API3170 | CD3 [BC33] |
| CT1056 | ALI/OPAI3170 | CD3 [BC33] |
| CT1056 | ACI/API3152 | CD3 [LN10] |
| CT1056 | CM/PM 110 | CD3 T-Cell (M) |
| CT1056 | OPAI110 | CD3 T-cell (M) |
| CT1056 | CP/PP215 | CD3(P) |
| CT1056 | PM/IP031 | CD30 (Ki-1) |
| CT1056 | CM/PM346 | CD30 (Ki-1) |
| CT1056 | PM074 | CD30 Cocktail |
| CT1056 | CM/PM/OAI131 | CD31 (PECAM-1) |
| CT1056 | CM/PM347 | CD31 |
| CT1056 | ACI/API3116 | CD33 |
| CT1056 | OPAI084 | CD34 |
| CT1056 | CM/PM/IP/OAI/ALI/AVI | CD34 |
| CT1056 | AVI167 | CD38 |
| CT1056 | CM/PM153 | CD4 (Helper/Inducer) |
| CT1056 | API3209 | CD4 (RM) |
| CT1056 | ACI/API3148 | CD4 [4B12] |
| CT1056 | API3157DSAA | CD4 + CD8 |
| CT1056 | CM/PM/IP005 | CD43 |
| CT1056 | CM/PM318 | CD44 |
| CT1056 | PM380 | CD44 |
| CT1056 | CM/PM006 | CD45RO [UCHL-1] |
| CT1056 | CM/PM/OAI099 | CD5 (M) |
| CT1056 | CM/PM/OAI164 | CD56 |
| CT1056 | CM/PM/OAI007 | CD57 (Natural Killer Cell) |
| CT1056 | ALI/AVI033 | CD68 [KP1] |
| CT1056 | OPAI033 | CD68 [KP1] |
| CT1056 | CM/PM/IP/OAI033 | CD68 [KP1] |
| CT1056 | CM/PM/OAI158 | CD7 |
| CT1056 | ACI/API3110 | CD71 |
| CT1056 | CM/PM067 | CD79a |

| Collective Term | Part Number (s) | Description |
|-----------------|--------------------|---------------------------|
| CT1056 | CRM/PRM311 | CD8 |
| CT1056 | ACI/API3160 | CD8 [C8/144B] |
| CT1056 | OPAI3160 | CD8 [C8/144B] |
| CT1056 | ACI/API3219 | CD8 [C8/1779R] |
| CT1056 | OPAI392 | CD99 |
| CT1056 | CME/PME/ OAI392 | CD99 |
| CT1056 | ACI/API3111 | CDH17 (M) |
| CT1056 | OPAI/ALI226 | CDX2 |
| CT1056 | CM/PM/IP/OAI226 | CDX2 |
| CT1056 | API3135DS | CDX2 (M) + CDH17 (RM) |
| CT1056 | ACI/API3144 | CDX2 (RM) |
| CT1056 | ACI/API/AVI3184 | CDX2 [BC39] |
| CT1056 | PM367DS | CDX2 + CK7 |
| CT946 | ORI6031K | Chamber Cleaning Kit |
| CT1056 | ALI/AVI010 | Chromogranin A |
| CT1056 | OPAI010 | Chromogranin A |
| CT1056 | CM/PM/IP OAI010 | Chromogranin A |
| CT1056 | API/IPI/ OAI3154DS | CK HMW + p63 + AMACR (RM) |
| CT1056 | OPAI3154 | CK HMW + p63 + AMACR (RM) |
| CT1056 | OAI3124K | CK HMW + p63, 2X |
| CT1056 | OPAI235 | CK5 + p63 |
| CT1056 | PM235 | CK5 + p63 |
| CT1056 | PM/OAI360DS | CK5/14 + p63 + CK7/18 |
| CT1056 | OPAI360 | CK5/14 + p63 + CK7/18 |
| CT1056 | OPAI225 | CK5/14 + p63 + P504S |
| CT1056 | CRM/PRM/IP339 | CK7 |
| CT1056 | API3161 | CK8/18 (RM) |
| CT1056 | ACI/API3121 | Claudin-4 |
| CT1056 | ACI218 | Clusterin |
| CT1056 | AVI415 | c-Myc |
| CT1056 | ALI415 | c-Myc |
| CT1056 | CME/PME415 | c-Myc |
| CT1056 | CM/PM112 | Collagen IV |
| CT1056 | CRM/PRM306 | COX-2 |
| CT1056 | ACI/API3211 | CTLA-4 |
| CT1056 | ACI/API3220 | CTLA-4 [CAL49] |
| CT1056 | CRM/PRM/IPI307 | Cyclin D1 |
| CT1056 | CME/PME/ OAI432 | Cyclin D1 |
| CT1056 | ALI/ OPAI432 | Cyclin D1 |
| CT1056 | ALI/OPAI307 | Cyclin D1 |

| Collective Term | Part Number (s) | Description |
|-----------------|----------------------|--|
| CT1056 | PM081 | Cytokeratin [AE1] LMW |
| CT1056 | CM185 | Cytokeratin 14 (CK14) |
| CT1056 | PM176 | Cytokeratin 17 (CK17) |
| CT1056 | ACI/API3061 | Cytokeratin 18 (CK18) |
| CT1056 | CM/PM/OAI242 | Cytokeratin 19 (CK19) |
| CT1056 | OPAI062 | Cytokeratin 20 (CK20) |
| CT1056 | CM/PM/IP/OAI062 | Cytokeratin 20 (CK20) |
| CT1056 | CM/PM/OAI234 | Cytokeratin 5 (CK5) |
| CT1056 | CME/PME430 | Cytokeratin 5 (CK5) |
| CT1056 | ACI/API/OAI3025 | Cytokeratin 5/14 Cocktail |
| CT1056 | OPAI105 | Cytokeratin 5/6 (CK 5/6) |
| CT1056 | AVI/ALI105 | Cytokeratin 5/6 (CK 5/6) |
| CT1056 | CM/PM/IPI105 | Cytokeratin 5/6 (CK 5/6) |
| CT1056 | OPAI061 | Cytokeratin 7 (CK7) |
| CT1056 | CM/PM/IP/OAI061 | Cytokeratin 7 (CK7) |
| CT1056 | CM/PM/IP/OAI127 | Cytokeratin HMW (34βE12) |
| CT1056 | AVI127 | Cytokeratin HMW [34βE12] |
| CT1056 | OPAI127 | Cytokeratin HMW [34βE12] |
| CT1056 | OPAI056 | Cytokeratin LMW (8/18) |
| CT1056 | CM/PM/IP/ALI/AVI/OAI | Cytokeratin LMW 8/18 (LMW CK 8/18) |
| CT1056 | OPAI/ALI266 | D2-40 (Lymphatic Marker) |
| CT1056 | CM/PM/IP/OAI266 | D2-40 (Lymphatic Marker) |
| CT215 | PD900 | Da Vinci Green Diluent |
| CT215 | DA000-250-Kit | DAB Away |
| CT946 | OPRI6055 | DAB Buffer |
| CT215 | OPRI6054 | DAB Chromogen |
| CT215 | DB801 | DAB Chromogen Kit |
| CT215 | DS830 | DAB Sparkle |
| CT946 | DS854 | DAB Substrate Buffer |
| CT943 | DC2012-220V | DC2012 Decloaking Chamber NxGen (220v model) |
| CT943 | DC2008INTL | Decloaking Chamber™ Plus |
| CT943 | DC2002INTL | Decloaking Chamber™ Pro |
| CT215 | BRI4015 | Deep Space Black™ Chromogen Kit |
| CT946 | DNS001 | Denaturing Solution (Elution Step) |
| CT946 | BRI4044 | DepART Solution |
| CT943 | DRY2008INTL | Desert Chamber Pro |
| CT1056 | CM/PM/IP/OAI036 | Desmin |
| CT1056 | CM/PM419 | Desmoglein 3 |
| CT1056 | ACI/API3018 | Desmoglein 3 + CK5 |
| CT1056 | PPM428DS | Desmoglein 3 + Napsin A |

| Collective Term | Part Number (s) | Description |
|-----------------|-----------------|--|
| CT1056 | API3067 | Desmoglein 3 + p40 (M) |
| CT1056 | API3132DS | Desmoglein 3 + p40 (M) + Napsin A (RM) |
| CT946 | OPRI6001 | Dewax Solution 1 (DS1) |
| CT946 | OPRI6003 | Dewax Solution 2 (DS2) |
| CT946 | OPRI6004K | Dewax Solution Kit |
| CT946 | ORI6004K | Dewax Solution Kit |
| CT943 | BRI2006 | Diva Decloaker, 100X |
| CT943 | DV2004X | Diva Decloaker, 10X |
| CT943 | DV2005 | Diva Decloaker, 20X |
| CT943 | DV2004 | Diva Decloaker, RTU |
| CT946 | BRI4036 | DNA Hybridization Buffer |
| CT1056 | CM/PM/OAI385 | DOG1 |
| CT907 | ORI6049 | DS Enzyme |
| CT907 | OPRI6049 | DS Enzyme |
| CT907 | OPRI6060K | DS Enzyme |
| CT1056 | ACI/API3230 | E-Cadherin |
| CT1056 | CM/PM/IP170 | E-Cadherin |
| CT1056 | ACI/API3012 | E-Cadherin (RM) |
| CT946 | EM897 | EcoMount |
| CT215 | HTE | Eosin Y |
| CT946 | CB917 | EDTA Decloaker, 5X |
| CT1056 | ACI063 | Epidermal Growth Factor Receptor (EGFR) |
| CT1056 | CM/PM143 | Epithelial Membrane Antigen (EMA [Mc-5]) |
| CT1056 | ACI/API3038 | Epithelial Membrane Antigen (EMA) [E29] |
| CT353 | API111 | Epstein-Barr Virus (EBV) |
| CT1056 | ACI3147 | ERCC1 |
| CT1056 | CM/PM/OAI421 | ERG |
| CT1056 | ALI/OPAI421 | ERG |
| CT1056 | API3017 | ERG (M), 2X |
| CT1056 | API437DS | ERG-2 (ERG + CK5) |
| CT1056 | ACI/API054 | Estrogen Receptor (ER) [1D5] |
| CT1056 | API308 | Estrogen Receptor (ER) [6F11 + SP1] |
| CT1056 | ACI/API093 | Estrogen Receptor (ER) [6F11] |
| CT1056 | ACI/API/OAI301 | Estrogen Receptor (ER) [SP1] |
| CT1056 | CP/PP039 | Factor VIII |
| CT1056 | CM/PM/IP357 | Factor XIIIa |
| CT1056 | ALI/AVI/OPAI357 | Factor XIIIa |
| CT946 | OPRI6041 | Fast Red Buffer |
| CT215 | OPRI6040 | Fast Red Chromogen |
| CT215 | ORI6042K | Fast Red Chromogen Kit |

| Collective Term | Part Number (s) | Description |
|-----------------|-------------------|---|
| CT215 | FB813 | Ferangi Blue™ Chromogen Kit 2 |
| CT946 | FAD901 | Fluorescence Antibody Diluent |
| CT946 | FP001 | Fluoro Care Anti-Fade Mountant |
| CT1056 | BRI4006K | Folate Receptor alpha IHC Assay Kit |
| CT1056 | CM/PM411 | Follicle Stimulating Hormone (FSH) |
| CT1056 | API3164 | FOXP3 |
| CT1056 | ACI/API3197 | FOXP3 [86D] |
| CT1056 | ACI/API3174 | Galectin-3 |
| CT1056 | CM/PM/ALI/OAI405 | GATA-3 |
| CT1056 | OPAI405 | GATA-3 |
| CT1056 | API/AVI3173 | GATA-3 + Uroplakin II |
| CT1056 | PM317DS | GCDFP-15 + Mammaglobin |
| CT1056 | ACI/API3221 | GITR [CAL8] |
| CT1056 | CP/PP040 | Glial Fibrillary Acidic Protein (GFAP {P}) |
| CT1056 | CM/PM065 | Glial Fibrillary Acidic Protein (GFAP{M}) |
| CT1056 | CM/PM408 | GLUT-1 |
| CT1056 | ACI/API3009 | Glutamine Synthetase |
| CT1056 | CM/PM396 | Glypican-3 |
| CT1056 | ACI/API3202 | Granzyme B |
| CT1056 | CM/PM113 | Gross Cystic Disease Fluid Protein-15 (GCDFP-15) (Brst-2) |
| CT1056 | API/OAI3191 | H. pylori (RM) |
| CT1056 | CM407 | Heat Shock Protein 70 |
| CT1056 | OPAI383 | Helicobacter pylori |
| CT1056 | CM/PM/IP/ OAI 383 | Helicobacter pylori |
| CT1056 | CM/PM/OAI166 | Hepatocyte Specific Antigen (HSA) |
| CT355 | API108 | Herpes Simplex Virus 1&2 (HSV 1&2) |
| CT1056 | AVI057 | HMB45 |
| CT1056 | CM/PM/IP/OAI057 | HMB45 |
| CT1056 | OPAI057 | HMB45 |
| CT1056 | CM/PM/IPI165 | HMB45 + MART-1 + Tyrosinase |
| CT1056 | OPAI165 | HMB45 + MART-1 + Tyrosinase |
| CT1056 | OPAI210 | HMW CK Cocktail + p63 (Basal Cell Cocktail) |
| CT1056 | CM/PM210 | HMW CK Cocktail + p63 (Basal Cell Cocktail) |
| CT946 | HTR1001 | Hot Rinse, 25X |
| CT355 | ACI/API177 | HPV Cocktail Broad Spectrum (HPV- 1,6,11,16,18 and 31) |
| CT355 | ACI186 | HPV-16 (CAMVIR-1) |
| CT1056 | CP/PP124 | Human Chorionic Gonadotropin (hCG) beta |
| CT1056 | ACI/API3185 | Human IgG |
| CT946 | IED1203,1204 | I.E.D Unit |
| CT1056 | ACI/API3210 | IDO1 |

| Collective Term | Part Number (s) | Description |
|-----------------|-----------------|--|
| CT1056 | ACI/API 3266 | IFNG [IFNG/3996R] |
| CT1056 | CM414 | IGF-1R |
| CT1056 | ACI/API3115 | IgG4 (M) |
| CT946 | PWB941 | Immunocare PBS, 10X |
| CT946 | TWB943 | Immunocare TBS Wash Buffer, 10X |
| CT1056 | ACI/API3180 | IMP3 (RM) |
| CT1056 | CM/PM171 | Inhibin, Alpha |
| CT215 | IPS0001INTL | intelliPATH FLX Automated Slide Stainer |
| CT215 | IPK5010 | intelliPATH FLX™ DAB Chromogen Kit |
| CT215 | IPK5017 | intelliPATH FLX™ Fast Red Chromogen Kit |
| CT907 | IPE5007 | intelliPATH FLX™ Pepsin |
| CT946 | IPB5000 | intelliPATH FLX™ Peroxidase Blocking Reagent |
| CT907 | IPK5014 | intelliPATH FLX™ Pronase Kit |
| CT907 | IPK5003 | intelliPATH FLX™ Universal HRP Detection Kit, 80-100 tests |
| CT907 | IP498 | intelliPATH FLX™ Universal Negative Control |
| CT1056 | IPI4006K | intelliPATH™ Folate Receptor alpha IHC |
| CT946 | IP974 | intelliPATH™ Background Punisher |
| CT215 | IPK5027 | intelliPATH™ Ferangi Blue™ Chromogen Kit |
| CT215 | IPCS5006 | intelliPATH™ Hematoxylin |
| CT1056 | IPSC5004 | intelliPATH™ Multiplex Secondary Reagent 2 |
| CT907 | IPI5034 | intelliPATH™ Negative Control (ER/PR) |
| CT907 | IPK5011 | intelliPATH™ Universal HRP Detection Kit |
| CT215 | IPK5024 | intelliPATH™ Warp Red Chromogen Kit |
| CT946 | IPA5018 | intelliPrep Solution |
| CT215 | IQ1000INTL | IQ Kinetic Slide Stainer |
| CT215 | IQ2000INTL | IQ Kinetic Slide Stainer |
| CT215 | IQ3000INTL | IQ Kinetic Slide Stainer |
| CT215 | IQ1000INTL-NS | IQ Kinetic Slide Stainer Without Orbital Shaker |
| CT215 | IQ2000INTL-NS | IQ Kinetic Slide Stainer Without Orbital Shaker |
| CT215 | IQ3000INTL-NS | IQ Kinetic Slide Stainer Without Orbital Shaker |

| Collective Term | Part Number (s) | Description |
|-----------------|-----------------|--|
| CT946 | ORI6020K | ISH Dewax Solution Kit |
| CT907 | ORI6047K | ISH HRP Detection for ONCORE |
| CT907 | BRI4050K | ISH HRP Detection Kit Digoxigenin Labeled DNA Probes |
| CT946 | ORI6021 | ISH Retrieval (AR3) |
| CT907 | ORI6039K | ISHzyme ONCORE |
| CT1056 | API3159DS | Kappa (M) + Lambda (P) |
| CT1056 | ACI/API3149 | Kappa Light Chain [L1C1] |
| CT1056 | AVI325 | Ki-67 |
| CT1056 | ALI325 | Ki-67 |
| CT1056 | CRM/PRM/ OAI325 | Ki-67 |
| CT1056 | OPAI325 | Ki-67 |
| CT1056 | AVI/ALI3156 | Ki-67 [MIB-1] |
| CT1056 | API3156 | Ki-67 [MIB-1] |
| CT1056 | OPAI3156 | Ki-67 [MIB-1] |
| CT1056 | PPM240DS | Ki-67 + Caspase-3 |
| CT1056 | API3192DS | Ki-67 + CK7/8/18 |
| CT1056 | API3198DS | Ki-67 + pHH3 |
| CT1056 | PM237DS | L26 + CD3 |
| CT1056 | ACI/API3213 | LAG3 [CAL26] |
| CT1056 | ACI/API3063 | Lambda Light Chain [N10/2] |
| CT1056 | CM/PM/IP/OAI016 | Leukocyte Common Antigen (LCA) Cocktail |
| CT1056 | ALI/OPAI016 | Leukocyte Common Antigen (LCA) Cocktail |
| CT1056 | ACI/API3262 | LMO2 [SP51] |
| CT1056 | M1U539 | MACH 1 Universal HRP-Polymer Detection Kit |
| CT215 | MRCT523 | MACH 2 Double Stain 1 |
| CT215 | MRCT525 | MACH 2 Double Stain 2 |
| CT1056 | MALP521 | MACH 2 Mouse AP-Polymer |
| CT1056 | MHRP520 | MACH 2 Mouse HRP-Polymer |
| CT1056 | RALP525 | MACH 2 Rabbit AP-Polymer |
| CT1056 | RHRP520 | MACH 2 Rabbit HRP-Polymer |
| CT1056 | M2U522 | MACH 2 Universal HRP-Polymer Detection |
| CT907 | M3M532 | MACH 3 Mouse AP-Polymer Detection |
| CT1056 | MH540 | MACH 3 Mouse HRP-Polymer |
| CT907 | M3M530 | MACH 3 Mouse HRP-Polymer Detection |
| CT907 | M3R533 | MACH 3 Rabbit AP-Polymer Detection |
| CT907 | M3R531 | MACH 3 Rabbit HRP Polymer Detection |
| CT907 | BRI4005 | MACH 4 Universal AP Detection System |
| CT1056 | M4U536 | MACH 4 Universal AP Polymer Kit |
| CT1056 | M4U534 | MACH 4 Universal HRP-Polymer Detection |
| CT1056 | BRI4012 | MACH 4 Universal HRP-Polymer Detection System |



Biocare Medical LLC

| Collective Term | Part Number (s) | Description |
|-----------------|----------------------|--|
| CT1056 | PM/OAI269 | Mammaglobin (M) |
| CT1056 | API3186DS | MART-1 + Tyrosinase + pHH3 |
| CT1056 | API3165 | MART-1 + Tyrosinase + SOX10 |
| CT1056 | AVI3216 | MART-1 + Tyrosinase + SOX10 |
| CT1056 | OPA1077 | MART-1 Cocktail |
| CT1056 | CM/PM/IP/OAI077 | MART-1 Cocktail |
| CT1056 | ACI/API3131 | MASH1 |
| CT1056 | API3181 | MCM2 + TOP2A |
| CT1056 | OPA3181 | MCM2 + TOP2A |
| CT1056 | AVI/ALI/OPA3114 | Melan A (M) |
| CT1056 | ACI/API3114 | Melan A (M) |
| CT1056 | CM/PM078 | Melanoma Cocktail |
| CT1056 | ACI/API3175 | Mesothelin |
| CT1056 | CP290 | Microglia (Iba1) |
| CT1056 | AVI423 | Microphthalmia Transcription Factor (MiTF) |
| CT1056 | CM/PM423 | Microphthalmia Transcription Factor (MiTF) |
| CT1056 | PM423H | Microphthalmia Transcription Factor (MiTF) |
| CT1056 | ALI/OPA1220 | MLH-1 |
| CT1056 | CM/PM/IP/OAI/ AVI220 | MLH-1 |
| CT1056 | AVI3214 | MLH-1 [BC23] |
| CT1056 | ACI/API3214 | MLH-1 [BC23] |
| CT1056 | AVI403 | MOC-31 |
| CT1056 | CM/PM403 | MOC-31 |
| CT215 | PD901 | Monet Blue Diluent |
| CT907 | ORI6050 | Mouse Amp HRP Detection |
| CT907 | OPRI6050 | Mouse Amp HRP Detection |
| CT907 | BRI4049 | Mouse anti-Digoxigenin |
| CT907 | ORI6044 | Mouse AP Detection |
| CT907 | OPRI6044 | Mouse AP Detection |
| CT907 | ORI6007 | Mouse HRP Detection |
| CT907 | OPRI6007 | Mouse HRP Detection |
| CT1056 | OPA1219 | MSH2 |
| CT1056 | CM/PM/OAI/AVI219 | MSH2 |
| CT1056 | ALI219G7 | MSH2 |
| CT1056 | ALI/OPA1265 | MSH6 |
| CT1056 | CM/PM/IP/OAI/ AVI265 | MSH6 |
| CT1056 | AVI3215 | MSH6 [BC19] |



Biocare Medical LLC

| Collective Term | Part Number (s) | Description |
|-----------------|--------------------|--|
| CT1056 | ACI/API3215 | MSH6 [BC19] |
| CT1056 | CM231 | Mucin 5AC (Gastric Mucin) |
| CT907 | OPRI6061 | Multiplex Dection 1 |
| CT907 | OPRI6045 | Multiplex Detection 2 |
| CT907 | ORI6045 | Multiplex Detection 2 |
| CT1056 | CRM/PRM/ OAI352 | MUM-1 |
| CT1056 | OPAI352 | MUM-1 |
| CT1056 | API3194DS | MUM-1 + CD56 |
| CT1056 | CM/PM/IP/OAI079 | Muscle Specific Actin (MSA) |
| CT353 | ACI/API140 | Mycobacterium tuberculosis (TB) |
| CT907 | PP023 | Myeloperoxidase |
| CT1056 | CM/PM115 | Myogenin |
| CT1056 | AVI434 | Napsin A |
| CT1056 | CM/PM/ IPI/ OAI388 | Napsin A |
| CT1056 | PP434 | Napsin A |
| CT1056 | OPAI388 | Napsin A |
| CT1056 | AVI388 | Napsin A |
| CT1056 | ACI/API3043 | Napsin A (RM) |
| CT1056 | ACI369 | Nerve Growth Factor Receptor |
| CT1056 | CM/PM066 | Neurofilament |
| CT1056 | CP/PP422 | NKX3.1 |
| CT1056 | ALI/OPAI422 | NKX3.1 |
| CT1056 | ACI/API3189 | NKX3.1 (RM) |
| CT946 | CB911 | Nuclear Decloaker, 10X |
| CT215 | ORI6056K | ONCORE DAB Chromogen |
| CT946 | OPRI6005 | ONCORE PRO Antigen Retrieval 2 (AR2) |
| CT943 | ONCPRO0001 | ONCORE PRO Automated Slide Staining System |
| CT946 | OPRI6056K | ONCORE Pro DAB Chromogen |
| CT946 | OPRI6042K | ONCORE Pro Fast Red Chromogen |
| CT1056 | API3011DS | p120 + E-cadherin |
| CT1056 | ACI/API3008 | p120 Catenin |
| CT1056 | API3246DS | p16 + Ki-67 |
| CT1056 | API3256DS | p16 + PRAME |

| Collective Term | Part Number (s) | Description |
|-----------------|-------------------------|--|
| CT1056 | ACI/API/AVI3231 | p16 INK4a |
| CT1056 | OPAI3231 | p16 INK4a [BC42] |
| CT1056 | CM354 | p21 |
| CT1056 | ACI/API/AVI/IPI/OAI3066 | p40 (M) |
| CT1056 | API3079 | p40 (M), 3X (Prostate) |
| CT1056 | ACI/API/ALI/AVI3030 | p40 (P) |
| CT1056 | OPAI3030 | p40 (P) |
| CT1056 | ACC3066 | p40 [BC28] BSA Free |
| CT1056 | API3172 | p40 + Uroplakin II |
| CT1056 | AVI298 | p53 |
| CT1056 | CME/PME298 | p53 |
| CT1056 | OPAI298 | p53 |
| CT1056 | CM/PM042 | p53 Tumor Suppressor Protein (M) |
| CT1056 | CM/PM/OAI/IP/ VP163 | p63 |
| CT1056 | PM391DS | p63 + CK5 |
| CT1056 | PPM427DS | p63 + TRIM29 |
| CT1056 | API3070 | p63, 2X (Lung) |
| CT1056 | PM366 | p63-2X |
| CT1056 | OPAI011 | Pan Cytokeratin [AE1/AE3] |
| CT1056 | CM/PM/IPI/VP011 | Pan Cytokeratin [AE1/AE3] |
| CT1056 | CM/PM/IP/VP043 | Pan Cytokeratin [Lu-5] |
| CT1056 | CM/PM/IP/ OAI162 | Pan Cytokeratin Plus [AE1/AE3+ 8/18] |
| CT1056 | ACI/API/OIA/AVI3227 | Pan Cytokeratin Plus [AE1/AE3+ 8/18] |
| CT1056 | OPAI162 | Pan Cytokeratin Plus [AE1/AE3+8/18] |
| CT1056 | AVI162 | Pan Cytokeratin Plus [AE1/AE3+8/18] |
| CT1056 | API3035 | Pan Lymphoma Cocktail (LCA+CD20+CD3+CD43) |
| CT1056 | PM362DS | Pan Melanoma + Ki-67 |
| CT1056 | OPAI362 | Pan Melanoma + Ki-67 |
| CT1056 | PPM213DS | Pan Melanoma + S100 (Tyrosinase + MART-1 + S100) |
| CT1056 | CM/PM/OAI178 | Pan Melanoma Cocktail -2 [Tyrosinase and Mart-1] |
| CT1056 | ACI/API/AVI/ALI/OPAI | Pan TRK [RM423] |
| CT1056 | OPAI207 | PAX5 |
| CT1056 | CM/PM/OAI/ALI207 | PAX5 |
| CT1056 | CP/PP379 | PAX8 |
| CT1056 | OPAI379 | PAX8 |
| CT1056 | ACI/API/ OAI/ALI/AVI438 | PAX8 (M) |



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| Collective Term | Part Number (s) | Description |
|-----------------|--------------------------|---|
| CT1056 | ACI/API/ OAI/ALI/AVI438 | PAX8 (M) |
| CT1056 | OPAI438 | PAX8 (M) |
| CT946 | PBS940 | PBS Plus, 10X |
| CT1056 | ACI/API3137 | PD-1 |
| CT1056 | API3162 | PD-1 (RM) |
| CT1056 | ACI/API3224 | PD-1 [CAL20] |
| CT1056 | ACI/API3171 | PD-L1 |
| CT1056 | OPAI3171 | PD-L1 |
| CT1056 | AVI3171 | PD-L1 |
| CT946 | PXA969 | PeroxAbolish |
| CT946 | PX968 | Peroxidized 1 |
| CT946 | PX970 | Peroxidized Diluent |
| CT1056 | ACI/API3130 | pHH3 (RM) |
| CT1056 | API300 | PHOSPHO-EGFR |
| CT1056 | CP/PP404 | Phospho-Histone H3 |
| CT1056 | CRM/PRM350 | Placental Alkaline Phosphatase (PLAP) |
| CT1056 | CM/PM/IPI/AVI/ALI/OAI344 | PMS2 |
| CT907 | NC499 | Polymer Negative Control Serum (Mouse & Rabbit) |
| CT1056 | ACI/API/AVI/ALI/OPAI3252 | PRAME [EPR20330] |
| CT946 | ORI6024 | Probe Enhancer (RNA) |
| CT1056 | ACI/API/OAI424 | Progesterone Receptor (PR) [16] |
| CT1056 | API343 | Progesterone Receptor (PR) [PgR636] |
| CT1056 | ACI/API302 | Progesterone Receptor (PR) [SP2] |
| CT946 | PRB957 | Pronase Buffer |
| CT1056 | AVI3206 | Prostate Cocktail (CK5 + CK14 + p63) |
| CT1056 | PM364 | Prostate Cocktail-2X (CK5+CK14+p63) |
| CT1056 | ACI/API3163 | Prostein |
| CT907 | PR960 | Protease XXIV |
| CT1056 | ACI/API/OPAI/AVI/ALI3263 | PSAP [rACPP/1338] |
| CT1056 | CM/PM278 | PTEN (Tumor Suppressor) |
| CT1056 | ALI/OPAI278 | PTEN (Tumor Suppressor) |
| CT907 | ORI6043 | Rabbit AP Detection |
| CT907 | OPRI6043 | Rabbit AP Detection |
| CT907 | ORI6008 | Rabbit HRP Detection |
| CT907 | OPRI6008 | Rabbit HRP Detection |
| CT215 | PD905 | Renaissance Background Reducing Diluent |



Biocare Medical LLC

| Collective Term | Part Number (s) | Description |
|-----------------|-------------------------|---|
| CT215 | PD904 | Renoir Red Diluent |
| CT943 | RV1000X | Reveal Decloaker, 10X |
| CT943 | RV1000 | Reveal Decloaker, RTU |
| CT215 | PD912 | Revival Series Sampler |
| CT907 | RI0213 | RISH™ AP Detection Kit |
| CT907 | RI0208 | RISH™ Dual Detection Kit |
| CT355 | RPI0001 | RISH™ Epstein-Barr Encoded RNA (EBER) Probe |
| CT907 | RI0207 | RISH™ HRP Detection Kit |
| CT355 | RPI0004 | RISH™ Kappa Light Chain DNA Probe |
| CT355 | RPI0005 | RISH™ Lambda Light Chain DNA Probe |
| CT946 | RI0209 | RISH™ Retrieval, 10X |
| CT215 | RAEC810 | Romulin AEC Chromogen Kit |
| CT1056 | ACI/API3208 | ROR gamma T |
| CT1056 | ACI/API/ALI3240 | ROS1 [EPMGHR2] |
| CT215 | HTEP | Rubens Eosin-Phloxine |
| CT1056 | CP/PP/OAI021 | S100 Protein (P) |
| CT1056 | CM/PM128 | S100 Protein [15E2E2] (M) |
| CT1056 | ACI/API3237 | S100 Protein [4C4.9] (M) |
| CT1056 | AVI3237 | S100 Protein [4C4.9] (M) |
| CT1056 | OPAI3237 | S100 Protein [4C4.9] (M) |
| CT1056 | CM/PM/IP/OAI089 | S100 Protein Cocktail |
| CT1056 | ACI/API3010 | S100P |
| CT1056 | AVI384 | SALL4 |
| CT1056 | CM/PM/OAI384 | SALL4 |
| CT1056 | ACI/API3225 | SATB2 [EP281] |
| CT946 | SBT | Slide Brite |
| CT1056 | ACI/API3242 | SMAD4 [EP618Y] |
| CT1056 | CM/PM/IP/OAI001 | Smooth Muscle Actin (SMA) |
| CT1056 | CM/PM420 | Smooth Muscle Myosin Heavy Chain |
| CT1056 | CM/PM372 | Smoothelin |
| CT1056 | ACI/API/OAI/IP/AVI 3099 | SOX10 (M) |
| CT1056 | OPAI3099 | SOX10 (M) |
| CT1056 | AVI3120 | SOX11 (M) |
| CT1056 | ACI/API3120 | SOX11 (M) |
| CT1056 | ACI/API3109 | SOX2 |
| CT946 | BRI/ORA4039 | SSC Wash Buffer |
| CT1056 | CM/PM406 | β-Catenin |



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| Collective Term | Part Number (s) | Description |
|-----------------|----------------------|---|
| CT907 | STUHRP700 | Starr Trek Universal HRP Detection System |
| CT1056 | ACI/API3244 | STAT6 [YE361] |
| CT1056 | API/ALI/AVI/OPAI3250 | STAG1 |
| CT1056 | AVI371 | Synaptophysin |
| CT1056 | OPAI371 | Synaptophysin |
| CT1056 | CM/PM/IP/OAI371 | Synaptophysin |
| CT215 | NM-HEM | Tacha's Automated Hematoxylin |
| CT215 | HTBLU | Tacha's Bluing Solution |
| CT215 | HTBLUX | Tacha's Bluing Solution, 10X |
| CT946 | TWB945 | TBS Automation Wash Buffer, 20X |
| CT946 | TWB946 | TBS Automation Wash Buffer, 40X |
| CT1056 | CP/PP134 | Terminal Deoxynucleotidyl Transferase (TdT {P}) |
| CT1056 | CM/PM022 | Thyroglobulin Cocktail |
| CT1056 | AVI/ALI130 | TIA-1 |
| CT1056 | OPAI130 | TIA-1 |
| CT1056 | CM/PM130 | TIA-1 |
| CT1056 | ACI/API3254 | TIGIT [BC41] |
| CT1056 | ACI/API3045 | Topoisomerase II alpha |
| CT1056 | ACI/API135 | Treponema pallidum (Spirochete) |
| CT1056 | PP416 | TRIM29 |
| CT946 | TBS942 | Tris Buffer Saline (TBS) Plus, 10X |
| CT1056 | ALI/CM/PM/IP087 | TTF-1 |
| CT1056 | ACI/API/OAI3126 | TTF-1 [SPT24] |
| CT1056 | OPAI3126 | TTF-1 [SPT24] |
| CT1056 | PM425DS | TTF-1 + CK5 |
| CT1056 | PPM / IPI 394DS | TTF-1 + Napsin A |
| CT1056 | API3078DS | TTF-1 + Napsin A (RM) |
| CT1056 | API3141DS | TTF-1 + p40 (cRM) |
| CT946 | ORI6036K | Tubing Cleaning Kit |
| CT946 | OPRI6036K | Tubing Cleaning Kit |
| CT1056 | CM/PM002 | Tumor Associated Glycoprotein [B72.3] |
| CT907 | CM/PM/OAI155 | Tyrosinase |
| CT907 | ORI6013 | Universal Negative Control Serum |
| CT907 | NC498 | Universal Negative Control Serum |
| CT907 | OPRI6013 | Universal Negative Control Serum |
| CT1056 | API3001DS | Uro-2™ (CK20 + p53) |
| CT1056 | PM370TS | URO-3 Triple Stain (CD44+p53) with CK20 |



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| Collective Term | Part Number (s) | Description |
|-----------------|------------------------|---------------------------------|
| CT1056 | OPAI3051 | Uroplakin II |
| CT1056 | ACI/API/AVI/OAI3051 | Uroplakin II |
| CT1056 | API3094 | Uroplakin II + Uroplakin III |
| CT1056 | ACI/API3023 | Uroplakin III |
| CT215 | PD902 | Van Gogh Yellow Diluent |
| CT946 | BRI4001 | V-Blocker |
| CT1056 | ACI356 | VEGF |
| CT1056 | AVI048 | Vimentin |
| CT1056 | CM/PM/IP/OAI048 | Vimentin |
| CT1056 | CRM/PRM312 | Vimentin |
| CT215 | VPD901 | VP Monet Blue Diluent |
| CT215 | FR805 | Vulcan Fast Red Chromogen Kit 2 |
| CT215 | WR806 | Warp Red Chromogen Kit |
| CT215 | WR806MCK | Warp Red Chromogen Kit (Custom) |
| CT946 | ORI6012 | Wash Buffer |
| CT946 | OPRI6012 | Wash Buffer |
| CT1056 | ACI3238 | WT1 |
| CT1056 | API3238 | WT1 |
| CT1056 | CM/PM258 | WT1 (Wilms' Tumor) |
| CT1056 | ACI/API3238 | WT1 [rWT1/857] |
| CT1056 | ACI259 | ZAP-70 (LR) |
| CT946 | FRI7323 | ZipFISH™ Hybridization Buffer |
| CT1056 | ALI/AVIOPAI170 | E-cadherin |
| CT1056 | OPAI344 | PMS2 |
| CT1056 | ALI163 | P63 |
| CT1056 | ALI3066 | P40 (M) |
| CT1056 | ALI3231 | p16 INK4a [BC42] |
| CT1056 | ACI/API/AVI3245 | OX40/CD134 |
| CT1056 | ACI/API/AVI/ALI/OPAI32 | H3K27me3 [C36B11] |
| CT907 | OPRI6062 | Universal HRP Detection |
| CT1056 | OPAI001 | Smooth Muscle Actin (SMA) |
| CT1056 | OPAI403 | MOC-31 |
| CT1056 | AVI3254 | TIGIT [BC41] |
| CT1056 | API3260 | NKX3.1 [D2Y1A] |
| CT1056 | ACI3260 | NKX3.1 [D2Y1A] |
| CT1056 | AVI3260 | NKX3.1 [D2Y1A] |
| CT1056 | ALI3260 | NKX3.1 [D2Y1A] |
| CT1056 | OPAI3260 | NKX3.1 [D2Y1A] |
| CT946 | OPRI4039 | SSC Wash Buffer |



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| Collective Term | Part Number (s) | Description |
|-----------------|-----------------|------------------------------|
| CT907 | OPRI6047K | ONCORE Pro ISH HRP Detection |
| CT907 | OPRI6039K | ONCORE Pro ISHzyme Kit |
| CT946 | OPRI6020K | ONCORE Pro ISH Dewax Kit |
| CT907 | OPRI6021 | ISH Retrieval (AR3) |
| CT1056 | ALI3237 | S100 Protein [4C4.9] (M) |
| CT1056 | ALI3099 | SOX10 (M) |
| CT1056 | ACI3255 | PCNA [PC10] |
| CT1056 | API3255 | PCNA [PC10] |
| CT1056 | AVI3255 | PCNA [PC10] |
| CT1056 | ACI3253 | IDH1 R132H [IHC132] |
| CT1056 | API3253 | IDH1 R132H [IHC132] |
| CT1056 | ACI3251 | ATRX |
| CT1056 | API3251 | ATRX |
| CT1056 | ACI3258 | TIM3 [BLR033F] |
| CT1056 | API3258 | TIM3 [BLR033F] |
| CT1056 | ACI3273, | HLA-DR [TAL 1B5] |
| CT1056 | API3273 | HLA-DR [TAL 1B5] |
| CT1056 | ALI3273 | HLA-DR [TAL 1B5] |
| CT1056 | AVI3273 | HLA-DR [TAL 1B5] |
| CT1056 | OPAI3273 | HLA-DR [TAL 1B5] |
| CT1056 | ACI3272 | Glycophorin A [JC159] |
| CT1056 | API3272 | Glycophorin A [JC159] |
| CT1056 | OPAI3272 | Glycophorin A [JC159] |
| CT1056 | AVI3272 | Glycophorin A [JC159] |
| CT1056 | ALI3272 | Glycophorin A [JC159] |
| CT1056 | ACI3270 | CD19 (RM) [RM332] |
| CT1056 | API3270 | CD19 (RM) [RM332] |
| CT1056 | OPAI3270 | CD19 (RM) [RM332] |
| CT1056 | AVI3270 | CD19 (RM) [RM332] |
| CT1056 | ALI3270 | CD19 (RM) [RM332] |
| CT1056 | ACI3271 | VISTA [BLR035F] |
| CT1056 | API3271 | VISTA [BLR035F] |
| CT1056 | ACI3276 | Glucagon |
| CT1056 | API3276 | Glucagon |
| CT1056 | ALI3276 | Glucagon |
| CT1056 | AVI3276 | Glucagon |
| CT1056 | OPAI3276 | Glucagon |

End of Product List