AMPLIRUN® TOTAL

A RELIABLE QUALITY CONTROL SOURCE FOR NUCLEIC ACID TESTS

vircell
MICROBIOLOGISTS

Take Control, Molecular Control.

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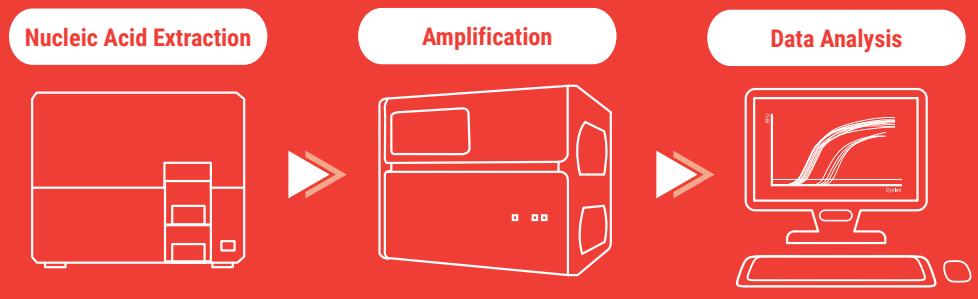
FULL PROCESS CONTROLS DESIGNED TO MONITOR THE ACCURACY AND PRECISION OF THE COMPLETE ANALYTICAL PROCESS



AmpliRun® Total

REGULATORY REQUIREMENTS REINFORCE THE NEED TO USE THIRD PARTY CONTROLS

Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

ISO 15189:2012 Medical Laboratories. Requirements for Quality and competence.

Controls independent of those produced by the manufacturer of the test or analyser should be used.

National Association of Testing Authorities (NATA) Australia. AS 4633 (ISO 15189) – Supplemental Requirements for accreditation in the field of Medical testing.

Quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure's performance in its entirety, including the procedure for calibration of the measurement.

Clinical and Laboratory Standards Institute (CLSI). C24-A3 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition, 6.2.1

For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

Clinical Laboratory Improvement Amendments (CLIA). Code of Federal Regulations – Title 42 Part 493 Laboratory requirements. §493.1256 Standard: Control procedures.

AMPLIRUN® TOTAL THIRD PARTY CONTROLS

Achieve independent assessment of your diagnostic devices and methods, comply with lab accreditation and improve patient care.

FEATURES

Whole pathogen controls with complete genome.
Quantified controls (low positive).
Shelf life: up to 2,5 years from date of manufacture.
Lyophilized presentation to ensure stability and avoid extra transport costs.
Monodose format.
Non-infectious microorganisms.
For IVD use.

MATRICES

Applicable for a range of matrices: plasma, swab, sputum, exudate, urine, stool and CSF.

MULTIPLE PLATFORM COMPATIBILITY

GeneXpert® (Cepheid), BD MAX™ (Becton Dickinson), Panther® (Hologic), FilmArray® (BioFire), ELITe InGenius® (ELITechGroup) or Liaison® MDX (Diasorin Molecular), among others.

CUSTOM SOLUTIONS

Vircell R&D team has both the experience and capacity to design, develop, and deliver customized biological controls for all kind of instruments and assays. We can produce variations of the existing products in terms of concentration or purification requirements, or we can customize entire new panels to meet your unique needs.

EXTERNAL RUN CONTROLS

Vircell is a leading provider of independent external run controls for Nucleic Acid Testing (NAT) with a long-term trajectory in infectious disease diagnostics.

AmpliRun® Total Controls are designed to be used as run controls for routine customer use to guarantee efficient nucleic acid extraction, amplification and detection. These inactivated whole-organism positive controls are provided in a matrix that mimics different human samples formulated to produce low level positive results at a clinically significant concentration. The control should be extracted and amplified alongside unknown samples and treated in an identical manner to a clinical specimen.

Each single-use vial is intended to help laboratories monitor and maintain consistent, accurate and meaningful performance of their molecular infectious diseases assays.

Quality control practices are essential in the routine molecular diagnostic laboratories for infectious diseases to ensure accuracy and reproducibility of lab test results. Start guaranteeing today the integrity and confidence of your results with **AmpliRun® Total Controls**.

RESPIRATORY INFECTIONS

AMPLIRUN® TOTAL **ATYPICAL BACTERIAL PNEUMONIA** CONTROL (SWAB)

Code: MBTC022-R
Analytes: *Bordetella pertussis, Chlamydophila pneumoniae, Chlamydophila psittaci, Coxiella burnetii, Legionella pneumophila, Mycoplasma pneumoniae*
Matrix: Swab
Copies/vial: 10,000 to 25,000
Fill volume: 500 µL
Copies/ml: 35,000
Kit size: 10 vials

AMPLIRUN® TOTAL **FLU A/FLU B/RSV** CONTROL (SWAB)

Code: MBTC028
Analytes: Influenza A, influenza B, RSV
Matrix: Swab
Copies/vial: 10,000 to 25,000
Fill volume: 500 µL
Copies/ml: 35,000
Kit size: 10 vials

AMPLIRUN® TOTAL **RESPIRATORY VIRAL PANEL** CONTROL (SWAB)

Code: MBTC020
Analytes: Adenovirus 4, coronavirus, influenza A H3N2, influenza B, novel influenza A H1N1, parainfluenza 1, parainfluenza 2, parainfluenza 3, RSV (subtype A), RSV (subtype B)
Matrix: Swab
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Copies/ml: 35,000
Kit size: 10 vials

TUBERCULOSIS INFECTIONS

AMPLIRUN® TOTAL **MDR-TB VERIFICATION & CONTROL PANEL** (SPUTUM)

Code: MBTC027
Analytes: 2 vials x *Mycobacterium tuberculosis*
2 vials x *Mycobacterium tuberculosis* RIF resistant rpoB mutation (S531L)
2 vials x *Mycobacterium tuberculosis* RIF resistant rpoB mutation (H526D)
2 vials x *Mycobacterium tuberculosis* INH RESISTANT katG mutation (S315T)
2 vials x *Mycobacterium tuberculosis* INH RESISTANT inhA mutation (C15T)
Matrix: Sputum
Copies/vial: 20,000 to 50,000
Fill volume: 1 mL
Copies/ml: 35,000
Kit size: 10 vials (5x2)

AMPLIRUN® TOTAL **MTB** CONTROL (SPUTUM)

Code: MBTC013
Analytes: *Mycobacterium tuberculosis*
Matrix: Sputum
Copies/vial: 20,000 to 50,000
Fill volume: 1 mL
Copies/ml: 35,000
Kit size: 10 vials

AMPLIRUN® TOTAL **MTB INH RESISTANT** CONTROL (SPUTUM)

Code: MBTC015
Analytes: 5 vials x *Mycobacterium tuberculosis* katG mutation (S315T)
5 vials x *Mycobacterium tuberculosis* inhA mutation (C15T)
Matrix: Sputum
Copies/vial: 20,000 to 50,000
Fill volume: 1 mL
Copies/ml: 35,000
Kit size: 10 vials (2x5)

AMPLIRUN® TOTAL **MTB RIF RESISTANT** CONTROL (SPUTUM)

Code: MBTC014
Analytes: 5 vials x *Mycobacterium tuberculosis* rpoB mutation (S531L)
5 vials x *Mycobacterium tuberculosis* rpoB mutation (H526D)
Matrix: Sputum
Copies/vial: 20,000 to 50,000
Fill volume: 1 mL
Copies/ml: 35,000
Kit size: 10 vials (2x5)

GASTROINTESTINAL INFECTIONS

AMPLIRUN® TOTAL **CLOSTRIDIUM DIFFICILE RT027** CONTROL (STOOL)

Code: MBTC026-R
Analyte: *Clostridium difficile* RT027
Matrix: Stool
Copies/vial: 300,000 to 750,000
Fill volume: 500 µL
Copies/ml: 35,000
Kit size: 10 vials

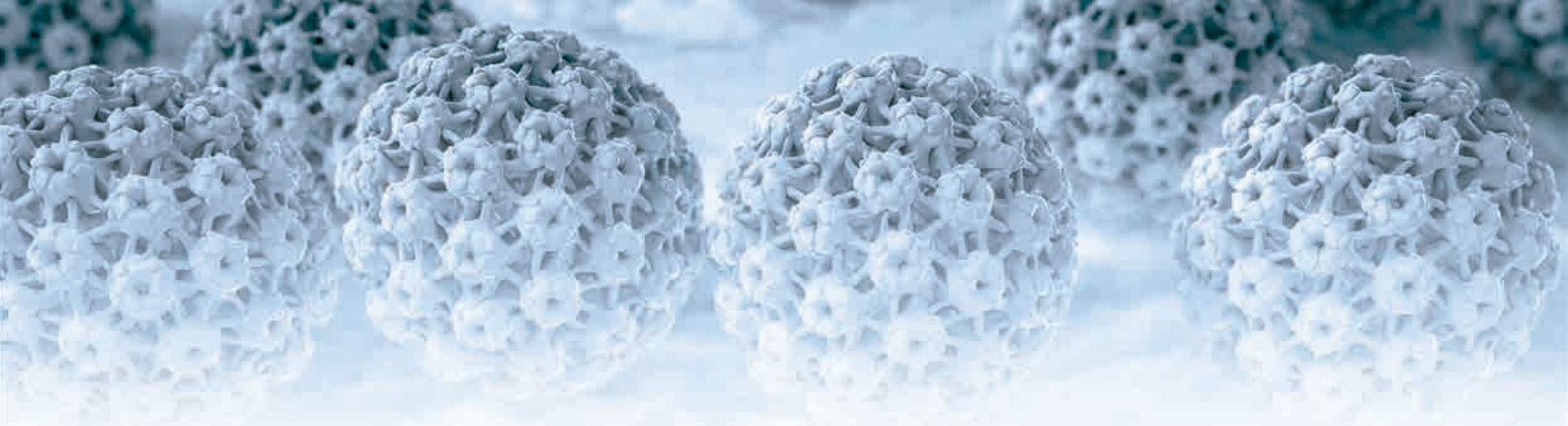
AMPLIRUN® TOTAL **GASTROINTESTINAL BACTERIAL PANEL** CONTROL (STOOL)

Code: MBTC021
Analytes: *Campylobacter jejuni, Clostridium difficile, Escherichia coli (EHEC), Salmonella enteritidis, Shigella flexneri, Yersinia enterocolitica*
Matrix: Stool
Copies/vial: 10,000 to 25,000
Fill volume: 500 µL
Copies/ml: 35,000
Kit size: 10 vials

MONONUCLEOSIS INFECTIONS

AMPLIRUN® TOTAL **EBV** CONTROL (PLASMA)

Code: MBTC019
Analyte: Epstein-Barr virus (International Units - EBV B95-8 strain)
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Copies/ml: 35,000
Kit size: 10 vials



SEXUALLY TRANSMITTED INFECTIONS

AMPLIRUN® TOTAL **CT/NG** CONTROL (EXUDATE)

Code: MBTC006
Analytes: *Chlamydia trachomatis, Neisseria gonorrhoeae*
Matrix: Exudate
Copies/vial: 2,500 to 10,000
Fill volume: 1 mL
Copies/ml: 5,000
Kit size: 10 vials

AMPLIRUN® TOTAL **CT/NG** CONTROL (URINE)

Code: MBTC003
Analytes: *Chlamydia trachomatis, Neisseria gonorrhoeae*
Matrix: Urine
Copies/vial: 2,500 to 10,000
Fill volume: 1 mL
Copies/ml: 5,000
Kit size: 10 vials

AMPLIRUN® TOTAL **CT/NG/TV/MGE** CONTROL (SWAB)

Code: MBTC024-R
Analytes: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium*
Matrix: Swab
Copies/vial: 20,000 to 50,000
Fill volume: 1 mL
Copies/ml: 35,000
Kit size: 10 vials

VECTOR-BORNE INFECTIONS

AMPLIRUN® TOTAL **ZIKV-DENV-CHIKV** CONTROL (PLASMA)

Code: MBTC023
Analytes: Zika virus, dengue virus (1-4), chikungunya virus
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Copies/ml: 35,000
Kit size: 10 vials

TORCH INFECTIONS

AMPLIRUN® TOTAL **CMV** CONTROL (PLASMA)

Code: MBTC018-R
Analytes: Cytomegalovirus (International Units - hCMV Merlin strain)
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µl
Copies/ml: 35,000
Kit size: 10 vials

AMPLIRUN® TOTAL **HSV-1/HSV-2** CONTROL (CSF)

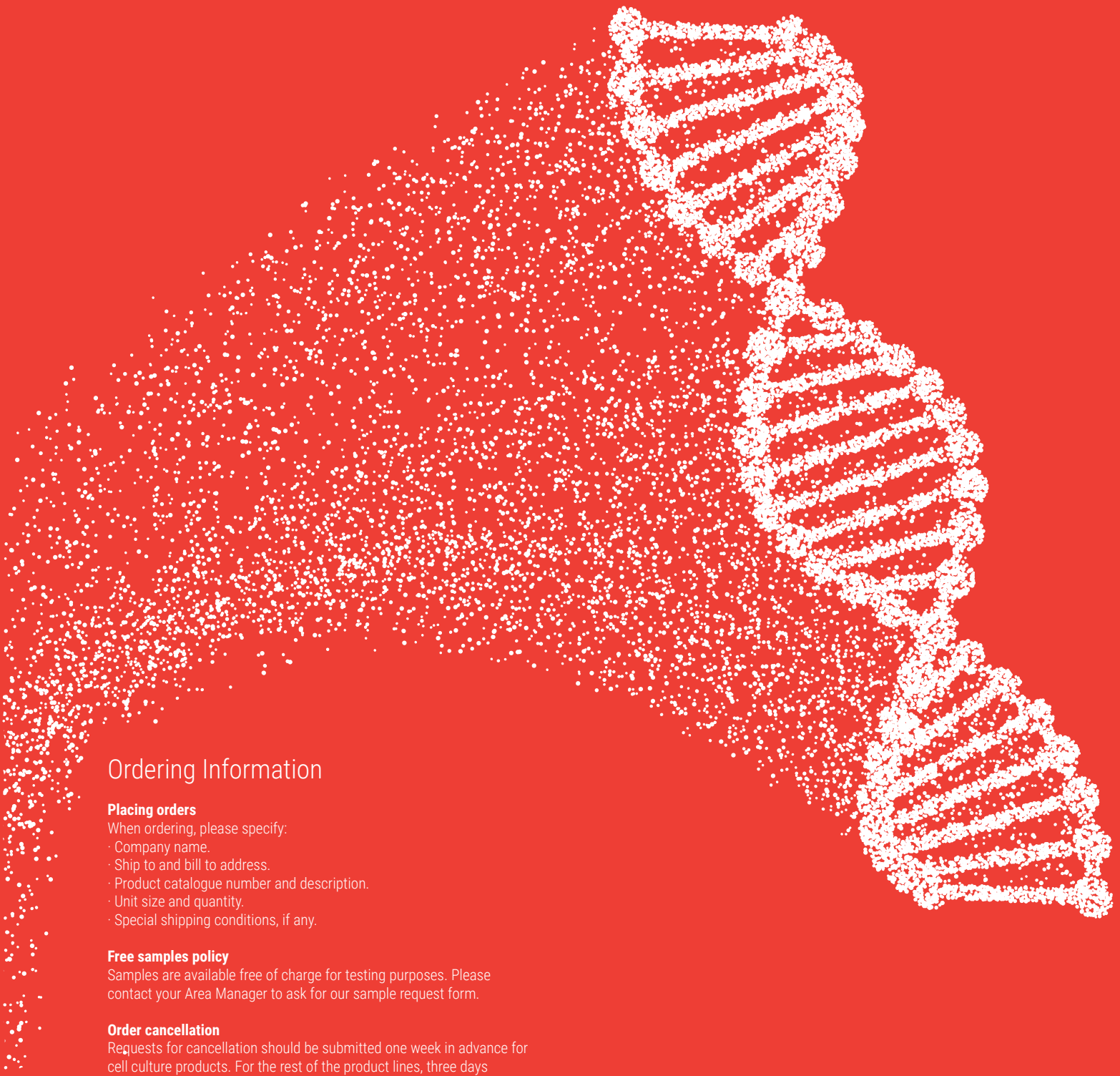
Code: MBTC009
Analytes: Herpes simplex virus 1 & 2
Matrix: CSF
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Copies/ml: 35,000
Kit size: 10 vials

AMPLIRUN® TOTAL **HSV-1/HSV-2** CONTROL (PLASMA)

Code: MBTC012
Analytes: Herpes simplex virus 1 & 2
Matrix: Plasma
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Copies/ml: 35,000
Kit size: 10 vials

AMPLIRUN® TOTAL **HSV-1/HSV-2/VZV** CONTROL (EXUDATE)

Code: MBTC016
Analytes: Herpes simplex virus & Varicella-zoster virus
Matrix: Exudate
Copies/vial: 4,000 to 10,000
Fill volume: 200 µL
Copies/ml: 35,000
Kit size: 10 vials



Ordering Information

Placing orders
When ordering, please specify:
· Company name.
· Ship to and bill to address.
· Product catalogue number and description.
· Unit size and quantity.
· Special shipping conditions, if any.

Free samples policy
Samples are available free of charge for testing purposes. Please contact your Area Manager to ask for our sample request form.

Order cancellation
Requests for cancellation should be submitted one week in advance for cell culture products. For the rest of the product lines, three days advanced notice is required.

Terms and Conditions

Prices
Product price shall be the prices specified in our current price list on the date of order. We reserve the right to revise our prices at any time with at least 1 month prior notice. Unless we state otherwise in writing, all prices are ex-works.

The validity period for preorders/orders awaiting prepayment will be one month. After that time, order confirmation is required.

Technical Support

For technical assistance and product information, please visit our website or contact our Technical Service Department at customerservice@vircell.com

We strive to answer all emails within 24 hours, and most are answered in substantially less time.

RESPIRATORY INFECTIONS

AMPLIRUN® TOTAL ATYPICAL BACTERIAL PNEUMONIA CONTROL (SWAB)	MBTC022-
AMPLIRUN® TOTAL FLU A/FLU B/RSV (SWAB)	RMBTC028
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB)	MBTC020

MYCOBACTERIAL INFECTIONS

AMPLIRUN® TOTAL MDR-TB VERIFICATION & CONTROL PANEL (SPUTUM)	MBTC027
AMPLIRUN® TOTAL MTB CONTROL (SPUTUM)	MBTC013
AMPLIRUN® TOTAL MTB INH RESISTANT CONTROL (SPUTUM)	MBTC015
AMPLIRUN® TOTAL MTB RIF RESISTANT CONTROL (SPUTUM)	MBTC014

GASTROINTESTINAL INFECTIONS

AMPLIRUN® TOTAL CLOSTRIDIUM DIFFICILE RT027 CONTROL (STOOL)	MBTC026-R
AMPLIRUN® TOTAL GASTROINTESTINAL BACTERIAL PANEL CONTROL (STOOL)	MBTC021

MONONUCLEOSIS INFECTIONS

AMPLIRUN® TOTAL EBV CONTROL (PLASMA)	MBTC019

SEXUALLY TRANSMITTED INFECTIONS

AMPLIRUN® TOTAL CT/NG CONTROL (EXUDATE)	MBTC006
AMPLIRUN® TOTAL CT/NG CONTROL (URINE)	MBTC003
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)	MBTC024-R

VECTOR-BORNE INFECTIONS

AMPLIRUN® TOTAL ZIKV-DENV -CHIKV CONTROL (PLASMA)	MBTC023

TORCH INFECTIONS

AMPLIRUN® TOTAL CMV CONTROL (PLASMA)	MBTC018-R
AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (CSF)	MBTC009
AMPLIRUN® TOTAL HSV-1/HSV-2 CONTROL (PLASMA)	MBTC012
AMPLIRUN® TOTAL HSV-1/HSV-2/VZV CONTROL (EXUDATE)	MBTC016

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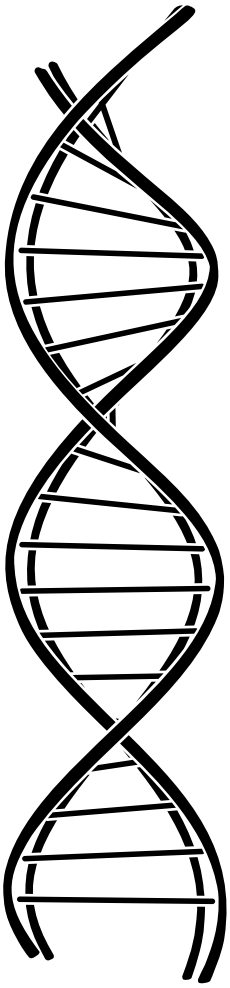
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