



INNOVITA⁺

No test too small, No matter too big.



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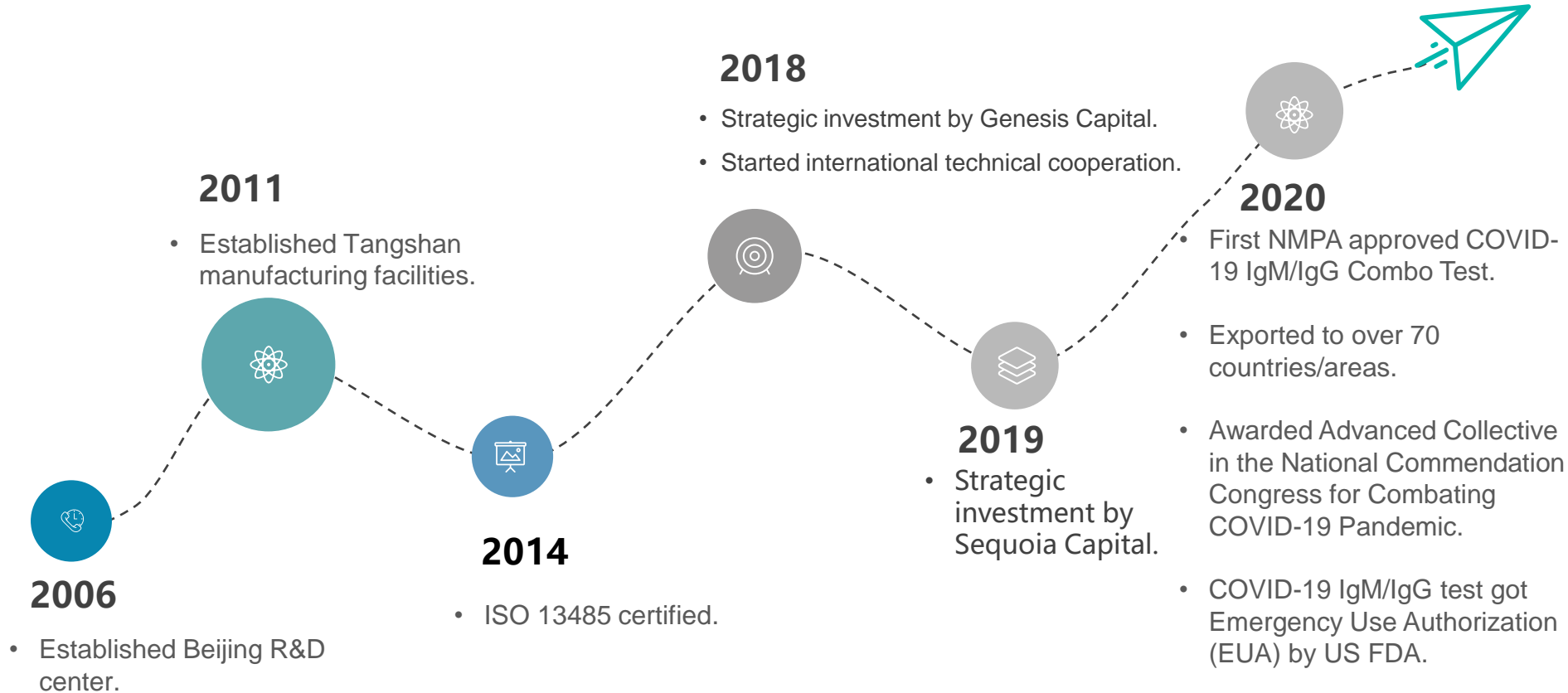
Company Profile

Innovita Biological Technology Co., Ltd. (together with its subsidiaries, collectively known as “INNOVITA”,) is a biotechnology company focusing on the research, development, production and sales of in vitro diagnostic POCT products. It consists of Innovita (Tangshan) , Innovita (Beijing) and Innovita (Guangzhou).

- Founded in 2006
- Set up R&D centers in Beijing and Guangzhou, and production base in Qian'an, Hebei



Development Process



Branches



Beijing R&D & Marketing Center

Establishment: 2006

Focus: R&D, manufacturing, marketing of in-vitro diagnostic product, including platforms such as immunodiagnosis, molecular diagnosis, and gene chips.

Qian'an Manufacturing & Logistic Center

Establishment: 2011

Facility: around 5,000 m² floor area, equipped with multiple production lines of colloidal gold, ELISA, PCR.

Certification: ISO 13485, CE, FDA, NMPA, etc.

Guangzhou R&D Center

Establishment: 2020

Focus: R&D of IVD technologies

Manufacturing Facilities



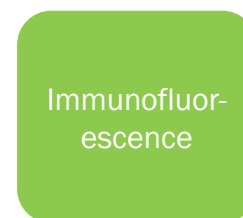
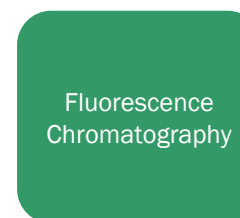
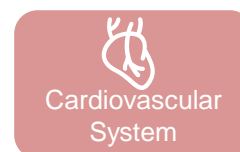
Manufacturing Facilities



Automatic Production Lines



Products & Platforms



Marketing Network

After years of development, Innovita already has a complete sales and service network, with sales channels covering 32 provinces and regions across China, and have exported to global markets such as Southeast Asia, Middle East, Africa, Latin America, Europe, etc.



Qualification



**High-tech
enterprises**



**Over 60
medical device
registration
certificates**



**Over 10
national
invention
patents**



**Annual output:
20,000,000
IVD tests**



**Exported to over
70 countries/areas**

Innovita 2019-nCoV Ab Test displayed on the national emergency platform for medicines and medical devices

- On February 28, 2020, Premier Li Keqiang inspected the national emergency platform for medicines and medical devices of COVID-19. Innovita 2019-nCoV Ab Test was displayed as the first NMPA approved IgM/IgG combo antibody test, which was reported on CCTV.



Innovita 2019-nCoV Ab Test named by Academician Zhong Nanshan

- On the afternoon of February 23, 2020, Academician Zhong Nanshan disclosed during a remote consultation in Guangzhou with the Guangdong medical team rushing to help Jingzhou that the National Medical Products Administration has approved two new test kits for 2019-nCoV, one of which is produced by Innovita (Tangshan) Biological Technology Co., Ltd.
- The kit uses the colloidal gold method, which can detect the IgM antibody in the patient's body. The IgM antibody can be detected on the 7th day of the patient's infection or the 3rd day of the onset, which is very helpful for the patient's further diagnosis. Zhong Nanshan said: "Patients can quickly be identified for a good diagnosis. This can help us quickly separate normal people from infected ones."



Advanced Collective Award

National Commendation Congress for Combating COVID-19 Pandemic

10:00 am Sept. 8 2020 at the Great Hall of the People

Innovita awarded Advanced Collective



Combating Pandemic



International Certification-2019-nCoV Ab Test



Acknowledgment Letter

3/3/2021

Young Wang, M.D.
Wanda Henry Co.
4426 Prancing Deer Drive
Ellicott City, MD 21043
UNITED STATES

FDA EUA

Dear Young Wang, M.D.:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA210191

Received: 3/3/2021

Applicant: Innovita (Tangshan) Biological Technology Co., LTD

Device: Innovita 2019-nCoV Ag Test (Latex Chromatography Assay)


We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,


Center for Devices and Radiological Health

		<h1>CIBG Netherlands</h1>
<p>CIBG Centrum voor Informatiegeografische Bestuurlijke Gegevens</p>	<p>Verrekenner</p> <p>Verrekenner Verrekenner Verrekenner Verrekenner Verrekenner</p> <p>Verrekenner voor de verwerking van de gegevens</p>	<p>CIBG Centrum voor Informatiegeografische Bestuurlijke Gegevens</p>
<p>4 december 2019, 10:00 uur, 10:00 uur</p> <p>DEBIS Bureau B.V. 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, </p>		

Salute Italy



Ministero della Sanità



OGEI
Osservatorio
Geografico
Economico
Italiano

Oggetto: Hungary

Descrizione dell'attività:

Analisi dei dati relativi alla diffusione della COVID-19 in Italia, con particolare riferimento alla regione Lazio.

Obiettivo: Fornire informazioni aggiornate sulla situazione epidemiologica e sanitaria della regione.

Metodologia: Analisi dei dati provenienti dai sistemi di sorveglianza e dai database regionali.

Periodo di riferimento: Dal 1° gennaio al 31 dicembre 2020.

Fonte dei dati: Ministero della Sanità, Regione Lazio, ASL Roma 1, ASL Roma 2, ASL Roma 3, ASL Roma 4, ASL Roma 5, ASL Roma 6, ASL Roma 7, ASL Roma 8, ASL Roma 9, ASL Roma 10, ASL Roma 11, ASL Roma 12, ASL Roma 13, ASL Roma 14, ASL Roma 15, ASL Roma 16, ASL Roma 17, ASL Roma 18, ASL Roma 19, ASL Roma 20, ASL Roma 21, ASL Roma 22, ASL Roma 23, ASL Roma 24, ASL Roma 25, ASL Roma 26, ASL Roma 27, ASL Roma 28, ASL Roma 29, ASL Roma 30, ASL Roma 31, ASL Roma 32, ASL Roma 33, ASL Roma 34, ASL Roma 35, ASL Roma 36, ASL Roma 37, ASL Roma 38, ASL Roma 39, ASL Roma 40, ASL Roma 41, ASL Roma 42, ASL Roma 43, ASL Roma 44, ASL Roma 45, ASL Roma 46, ASL Roma 47, ASL Roma 48, ASL Roma 49, ASL Roma 50, ASL Roma 51, ASL Roma 52, ASL Roma 53, ASL Roma 54, ASL Roma 55, ASL Roma 56, ASL Roma 57, ASL Roma 58, ASL Roma 59, ASL Roma 60, ASL Roma 61, ASL Roma 62, ASL Roma 63, ASL Roma 64, ASL Roma 65, ASL Roma 66, ASL Roma 67, ASL Roma 68, ASL Roma 69, ASL Roma 70, ASL Roma 71, ASL Roma 72, ASL Roma 73, ASL Roma 74, ASL Roma 75, ASL Roma 76, ASL Roma 77, ASL Roma 78, ASL Roma 79, ASL Roma 80, ASL Roma 81, ASL Roma 82, ASL Roma 83, ASL Roma 84, ASL Roma 85, ASL Roma 86, ASL Roma 87, ASL Roma 88, ASL Roma 89, ASL Roma 90, ASL Roma 91, ASL Roma 92, ASL Roma 93, ASL Roma 94, ASL Roma 95, ASL Roma 96, ASL Roma 97, ASL Roma 98, ASL Roma 99, ASL Roma 100.

Obiettivi:

- Analizzare i dati relativi alla diffusione della COVID-19 in Italia, con particolare riferimento alla regione Lazio.
- Fornire informazioni aggiornate sulla situazione epidemiologica e sanitaria della regione.
- Identificare le aree a rischio e le popolazioni vulnerabili.
- Proporre interventi di prevenzione e controllo.

Attività:

- Analisi dei dati relativi alla diffusione della COVID-19 in Italia, con particolare riferimento alla regione Lazio.
- Elaborazione di report e dashboard.
- Partecipazione a riunioni e workshop.
- Collaborazione con le ASL e i centri di ricerca.

Struttura organizzativa:

Il progetto è coordinato dal Ministero della Sanità, con la partecipazione della Regione Lazio e delle ASL.

Finanziamento:

Il progetto è finanziato dal Ministero della Sanità, con la partecipazione della Regione Lazio e delle ASL.

Valutazione:

Il progetto sarà valutato in base ai risultati ottenuti e alla soddisfazione degli stakeholder.

Conclusioni:

Il progetto ha fornito informazioni preziose sulla situazione epidemiologica e sanitaria della regione Lazio, consentendo di identificare le aree a rischio e le popolazioni vulnerabili.

Raccomandazioni:

È necessario continuare a monitorare la situazione e implementare interventi di prevenzione e controllo.

Prospettive:

Il progetto sarà ripetuto in futuro, con l'obiettivo di migliorare la qualità dei dati e l'efficacia degli interventi.

[illegible][illegible]

Figure 1 shows two sample pages from the 2015-2016 Mexico Country Report. The left page is from the ARCSA Ecuador report, and the right page is from the COFEPRIS Mexico report. Both pages are marked with red circular stamps and have a red 'CONFIDENTIAL' stamp at the bottom right.

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INFARMED
Portugal

CIBG
Netherlands

**FDA
Philippines**

[illegible][illegible]

ANMAT Argentina

scientific reports

Although several cases of family clusters with SARS-CoV-2 infection have been reported, there are still limited data governing conclusions from being drawn regarding the characteristics and laboratory findings in the COVID-19 population within family clusters. In the present study, we retrospectively collected 16 family clusters with COVID-19 and summarized the dynamic profiles of the clinical characteristics, laboratory findings, immune markers, treatment and prognosis of this population. Furthermore, we also compared clinical and laboratory data between the SARS-CoV-2 infection with family cluster ($n = 13$) and those without family cluster ($n = 3$). We demonstrated that the duration of SARS-CoV-2 infection might be extended based on the dynamic profiles of the above-mentioned parameters. The results of this study may provide a reference for the treatment and prognosis of COVID-19 patients at the end of the SARS-CoV-2 pandemic period. Furthermore, the obtained results demonstrated that similar basic characteristics and clinical findings exist between the cases with SARS-CoV-2 and without family clusters. The serum level of ferritin might have a different biological function and be a new biomarker for the family cluster. Further studies with larger numbers of patients are required.

Laboratory findings for patients with SARS-CoV-2 infection. Specimens including serum, stool, and nasopharyngeal swabs were obtained and the presence of SARS-CoV-2 was confirmed using a RT-PCR assay (Shanghai Bioscience Medical Biotechnology Co., Ltd. Shanghai, China) according to the published protocol [10]. The serum samples were tested for the presence of SARS-CoV-2 using a commercial enzyme-linked immunosorbent assay (ELISA) kit (Inventiva Biological Technology Co., Ltd. Beijing, China) in accordance with the guideline. The serum biochemistry markers (COBAS Integris® 800, Roche Diagnostics, Germany) including aspartate aminotransferase, lactate aminotransferase, creatine dehydrogenase, creatine kinase, creatine kinase isoenzymes, and myoglobin were determined. The serum ferritin concentration was determined using a chemiluminescence immunoassay (CMIA) kit (Beckman Coulter, Brea, CA, USA). The serum concentrations of type B natriuretic peptide, interleukin-6, PCT and CRP were determined using the relevant enzyme-linked immunosorbent assay according to the standard protocol. The serum ferritin concentration was detected by an immunosorbent assay. All the laboratory tests were performed at the Laboratory of Infection Immunology, Shanghai Chongming District Diseases Hospital, Cheshuo College of Medicine, Shanghai University.

Methods: We did a randomized, double-blind, placebo-controlled, phase 3b trial at Shanghai City Lung Cancer Research Center, China. Control and Intervention in Human Population, China phase 3b study people aged 18–60 years, who were negative for serum-specific IgG/IgA antibodies against SARS-CoV-2 at the time of screening, were separated into two age groups (30–59 years and ≥60 years) and randomly assigned to receive vaccine or placebo in a two-dose schedule of 2 mg, i.g. or 8 mg on days 0 and 28. In phase 2, healthy adults (30–59 years) were randomly assigned (1:1:1) to receive vaccine or placebo on a single-dose schedule of 8 mg on day 0. In phase 3b, participants were randomly assigned to receive vaccine or placebo on a two-dose schedule of 2 mg, i.g. or 8 mg on days 0 and 28. Participants were randomly assigned by stratified block randomization (block size eight) and allocated (3:1) to receive vaccine or placebo. Group allocation was concealed from participants, investigators, and outcome assessment. The primary outcomes were safety and tolerability. The secondary outcome was immunogenicity, assessed as the neutralizing antibody response against infectious SARS-CoV-2. This study is registered with www.chictr.org.

[illegible]

Funding National Program on Key Research Project of China, National Mega projects of China for Major Infectious Diseases, National Mega Projects of China for New Drug Creation, and Beijing Science and Technology Plan.

We did a dose-escalation, randomised, double-blind, placebo-controlled, phase 1/2 trial of an inactivated SARS-CoV-2 vaccine, BBIBP-CoV, in a single centre (Center for Disease Control and Prevention, Liangyan District, Shangqiu City, Henan Province, China). Participants were screened for SARS-CoV-2 infection by serology only before enrolment. Eligible participants were healthy people aged 18–80 years, who were negative for serum-specific IgM/IgG antibodies against SARS-CoV-2, as measured by a commercial kit (Innovita, China) at the time of screening. Exclusion criteria were a history of travelling to Hubei Province (China), regions outside of China, or regions with reported COVID-19 cases from December, 2019; a history of infection with SARS-CoV; fever, cough, runny nose, sore throat, diarrhoea, dyspnoea, or tachypnoea in the 14 days before vaccination; abnormalities in laboratory tests; pregnancy or lactation; allergy to any ingredient included in the vaccine; a history of seizures or mental illness; and being unable to comply with the study schedule. Laboratory tests included measurement of alkaline aminotransferase, aspartate aminotransferase, serum total bilirubin, creatinine, blood urea nitrogen, white blood cell count, haemoglobin, blood glucose, urinary protein, and urinary glucose.

doi:10.1371/journal.pone.0180776.g001

- Minimum Age: 18 Years
- Maximum Age: 80 Years
- Are Healthy Volunteers Accepted: Accepts Healthy Volunteers

- Gender Eligibility: All
- Minimum Age: 18 Years
- Maximum Age: 80 Years
- Are Healthy Volunteers Accepted: Accepts Healthy Volunteers

THANK YOU!



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INNOVITA

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